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# Outreach and Education in the Life Sciences

## A Case Study of the U.S. Department of Energy National Laboratories

RE Weller RL Burbank HA Mahy

March 2010



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Pacific Northwest National Laboratory Richland, Washington 99352

#### **Summary**

This project was intended to assess the impact of the U.S. Department of Energy's National Nuclear Security Agency (DOE/NNSA) -sponsored education and outreach activities on the Biological Weapons Convention (BWC) in DOE national laboratories. Key activities focused on a series of pilot education and outreach workshops conducted at ten national laboratories. These workshops were designed to increase awareness of the BWC, familiarize scientists with dual-use concerns related to biological research, and promote the concept of individual responsibility and accountability.

Staff at Pacific Northwest National Laboratory (PNNL) conducted a survey and series of focus groups to gauge retention of key concepts and lessons learned in the national laboratories, including individual awareness of dual-use risk; perceptions of the need for training; and opinions about the roles, responsibilities, and preventive measures related to life sciences research. The study also evaluated the need for future educational activities and assessed appropriate mechanisms and best practices for such efforts. Key findings were as follows:

- There is a variable level of awareness of dual-use risk. Understanding of dual-use issues often varies according to an individual's scientific discipline and activities. All participants had some level of awareness, but there were still significant gaps. Additionally, because the participant group is not necessarily a representative sample across laboratories, actual institutional awareness may be lower.
- Assessing dual-use risk is challenging. While the potential exists for misuse of almost all life science research, it is extremely difficult to characterize the potential risks and benefits of conducting that research and publishing the results. When the level of risk is unclear, scientists tend to categorize it as minimal and move forward with research and publication. Additional guidance and clarity for these scientists regarding what constitutes dual-use activities of concern is necessary.
- Scientists are concerned about the impact of guidelines. Many participants were clearly opposed to the development and implementation of mandatory guidelines that would constrain research or research publications; however, some saw value in voluntary guidelines or codes of conduct as awareness-raising tools.
- Despite a lack of time and resources, training is needed. Most participants saw value in the prospect of future training in this area; however, sufficient time and resources to undertake such training are lacking, and most scientists would be unmotivated to pursue such training independently. Participants identified universities as a particular target for training, and considered that university training would provide the framework for building and sustaining a culture of bioresponsibility that effectively blends ethics and BWC treaty obligations.
- **Develop a culture of responsibility**. Education on dual-use topics should be provided early and continually reinforced. There is significant value to developing a "culture of responsibility" that includes a shared awareness of security concerns.
- Engage young scientists. Participants repeatedly stated that it would be valuable to engage young scientists by working with academic institutions and professional societies, such as the American Society for Microbiology and American Society of Toxicology, to provide training.
- Organizations responsible for training in biosecurity and bioresponsibility need appropriate tools to accomplish their objectives. Organizations acting as the focal point for outreach and

training on biosecurity and dual-use concerns would most likely require additional tools and resources, support, and reasonable guidance. The format and efficacy of effective training tools will likely vary according to the audience. In addition to helping fulfill U.S. obligations under Article IV of the BWC, developing tools and providing training on biosecurity awareness can support international assistance and capacity building.

Evaluation of DOE's previous outreach and education efforts indicates that scientists would benefit from increased awareness of dual-use issues, and the availability of simple tools and guidelines could help in an objective assessment of risk.

#### **Recommendations for next steps include:**

- 1. Develop educational curriculum and tools for national laboratories using best practices for low-cost, sustainable deployment of these outreach efforts within the national laboratory complex. Case studies and concrete examples are needed to help clarify what is meant by "dual-use" in the life sciences (for example, how to assess both ambiguous cases and worst-case scenarios). Additionally, biosecurity and dual-use concerns should be framed in the context of broader issues, such as infectious disease surveillance, public health infrastructure, and effective countermeasures, to make biosecurity and dual-use training more clearly relevant to ongoing research.
- 2. Collaborate with other organizations in the development of training material. The DOE/NNSA education and outreach effort has been unique for training such a large group of laboratory scientists in biosecurity and dual-use considerations under the BWC. Sharing best practices in implementation could provide valuable input to other organizations.
- 3. Organize and/or participate in training and workshops. It is important for DOE to actively seek opportunities to remain engaged in the growing dialogue to raise awareness of biosecurity and dualuse issues. Organizing and holding seminars, collaborating with other organizations to plan workshops, and participating in thematic workshops planned by others would be effective ways to expose other audiences to this message, share educational materials and lessons learned—particularly with academic centers, international collaborators, Non-Governmental Organizations and countries interested in technical cooperation with the United States.

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#### 1.0 Introduction

Rapid developments in biotechnology and the life sciences bring significant benefits but also create new security challenges. In recent years, members of the scientific, security, and policy communities have raised concerns about the potential for misuse of biotechnology and life sciences knowledge, tools, and techniques for bioterrorism purposes. The dual-use nature of life sciences research means that research intended for beneficial purposes could be misapplied.

Upholding the nonproliferation objectives of the Biological and Toxin Weapons Convention (BWC) will rest increasingly on the expertise, judgment, and goodwill of individual scientists. Article IV of the BWC requires states to hold their citizens responsible for violations of the BWC, thus supporting the concept of individual responsibility. In fulfilling its BWC obligations, the U.S. government has passed a body of national implementing legislation that holds individuals criminally liable for such violations. However, the nature of life sciences research means that individuals are often unaware of the dual-use concerns related to biological research. Awareness and education are among the most effective tools for promoting responsible research and enhancing biosafety and biosecurity.

As part of U.S. efforts to address obligations under the BWC, the U.S. Department of Energy National Nuclear Security Agency (DOE/NNSA) has been pursuing a unique outreach and education program in its national laboratories that is designed to familiarize the more than 30,000 scientists and engineers working in the DOE complex with the BWC. The program began in 2005 with a workshop that brought together members of the scientific community, government representatives, and private industry to discuss concerns surrounding "dual-use" research and how to foster a sustainable culture of bioresponsibility.

The outcomes of these early discussions led by NNSA established initial requirements for a curriculum of outreach. In 2006, Pacific Northwest National Laboratory (PNNL) held a series of outreach and education workshops at ten DOE national laboratories. For these workshops, PNNL designed educational and training materials to inform scientists on national and individual obligations under the BWC.

The training identified aspects of research (including dual-use research) that may be subject to exploitation by those interested in pursuing biological weapons. The workshop also demonstrated how acts of responsible stewardship of biological knowledge and materials can help improve U.S. biosecurity and introduced the concept of codes of conduct.

An important outcome of the workshops was an improved understanding by scientists of the legal and political framework for biological weapons nonproliferation and an enhanced understanding of the diverse mechanisms for proliferation posed by research in the life sciences. The workshops also improved scientists' overall ability to recognize and respond to nonproliferation norms and requirements, as established in BWC Article IV, United Nations Security Council Resolution (UNSCR) 1540, other policies and international agreements. The workshops clearly demonstrated that education can enhance national compliance with biological weapon nonproliferation obligations.

<sup>&</sup>lt;sup>1</sup> http://www.fas.org/nuke/control/bwc/text/bwc.htm

<sup>&</sup>lt;sup>2</sup> http://www.state.gov/t/isn/c18943.htm

The workshop series was designed to give scientists an overview of the BWC and its inherent obligations as well as methods of compliance and awareness of proliferation potential. Article IV of the BWC requires each state to prohibit, "in accordance with its constitutional processes," activities on its territory that are proscribed under the Convention. Article IV also specifies measures to prohibit and prevent criminal activities within a territory under its jurisdiction or control. These strictures are the basis for national implementing legislation; however, they also imply that states must hold citizens responsible for violating the BWC, thereby introducing the concept of individual responsibility.

While implementing legislation is useful in providing national guidelines for fulfilling nonproliferation obligations, the pervasive dual-use nature of the life sciences and associated technologies makes them difficult to regulate without impeding the progress of scientific research. In this context, *self-regulation* through responsible behavior of the scientific community will be critical to maintain and strengthen compliance with the BWC and other nonproliferation objectives.

The series of workshops was designed to improve DOE national laboratory scientists' awareness of the requirements outlined by the BWC and other nonproliferation guidelines, thereby enhancing national compliance. Specific objectives of the workshops included:

- To educate scientists about U.S. obligations under the BWC, other international and national guidance;
- To enhance scientist awareness of proliferation concerns associated with dual-use research and technologies;
- To inform scientists of national and international efforts to develop codes of conduct and measures
  for reinforcing scientific ethics, including guidelines on dual-use and codes of conduct being
  developed by the National Science Advisory Board for Biosecurity (NSABB).

Curriculum of the workshops followed the outline below:

- I. Introduction, History, and Goals
- II. The Biological Weapons Convention: Key Principles and U.S. Obligations
  - a. Key Principles and Obligations
  - b. Gaps in Biological Weapons Nonproliferation
  - c. Ways to Strengthen the BWC
- III. Dual-Use in the Life Sciences
  - a. Definition of Dual-Use
  - b. Dual-Use Pathogens, Toxins, and Technologies
  - c. Considerations for Research and Experiments
- IV. Codes of Conduct in the Life Sciences
  - a. Current Oversight of Life Sciences Research
  - b. National and International Discussions Regarding Codes of Conduct (BWC, NSABB, etc.)
  - c. Potential Impact on Laboratories

The workshops were designed to lay the necessary foundation for a sustainable, long-term mechanism for outreach and education within the national laboratory system. Following the workshop series held across the DOE complex, PNNL conducted evaluations designed to measure the program's effectiveness

and participants' retention and application of key concepts and lessons learned. These evaluations, consisting of a survey and focus groups, also gauged awareness of the BWC and dual-use topics, and attitudes toward individual responsibility.

The quantitative technique—the survey—was analyzed in the report *Education and Outreach in the Life Sciences: Quantitative Analysis Report* (Appendix A). The qualitative measures (focus groups) are analyzed in *Education and Outreach in the Life Sciences: Qualitative Analysis Report* (Appendix B). A *Crosswalk Analysis Report* (Appendix C) was conducted, including the outcomes of both evaluations, to identify patterns and synchronicity across the findings.

This report summarizes key findings from this project, identifies needs for future educational activities, and discusses potential mechanisms for a sustainable education and outreach effort.

## 2.0 Methodology: Workshops, Survey, and Focus Groups

#### 2.1 Workshops

Of the more than 130 scientists who participated in the workshops, most were aligned primarily in biosciences, national security, and environmental health and safety divisions. Workshop communication and invitations were designed for individuals from these three areas. This was important to stimulate widespread communication and develop a sustainable educational strategy. These workshops were designed to introduce scientists to the BWC, acquaint them with the risks associated with dual-use research, promote communication with and among scientists, and educate scientists about their responsibility for safety and security. The pilot workshops were developed as "train-the-trainer" events to introduce key concepts and stimulate further discussion among key scientists and managers.

Initial communications occurred with senior laboratory management, who advocated the organization's support and buy-in and helped to ensure participation. Managers were invited to participate in the workshops, and they helped recruit the participation of appropriate senior scientists working in the life sciences and related disciplines. The approach recognized that senior scientists are often in the position to understand relevant science and policy concerns, and also tend to be communication hubs and mentors for younger scientists. Representatives from each laboratory's Institutional Biosafety Committee (IBC) were also invited to participate, as these individuals are often assigned responsibility for ensuring laboratory and project compliance with biosafety and biosecurity requirements. A number of workshop participants perform multiple roles in their organizations.

The workshops on average comprised 10 to 20 people and lasted 2 to 3 hours. To assess and finetune the material and process before the workshop series was launched at other national laboratories, PNNL hosted the pilot workshop at PNNL. Material and delivery for the upcoming workshops were adjusted based on reception and feedback results received during the pilot event. Table 2.1 lists those laboratories where the workshops were held and the number of participants from each site.

Table 2.1. Workshop Series Participating Laboratories and Research Areas

| Laboratory                                       | Number of Participants | Research Areas Represented   |
|--|------------------------|--|
| Argonne National Laboratory (ANL)                | 9                      | Biology, Environmental Science   |
| Brookhaven National Laboratory (BNL)             | 11                     | Biology, Environmental Sciences, Facilities & Operations, Nonproliferation & Security          |
| Idaho National Laboratory (INL)                  | 13                     | Biological Sciences, Emergency Management,<br>Environmental Health & Safety, National Security |
| Lawrence Berkeley National Laboratory (LBNL)     | 9                      | Ecology, Environment, Homeland Security  |
| Lawrence Livermore National<br>Laboratory (LLNL) | 15                     | Biosciences, Environmental Health & Safety,<br>National Security                               |
| Los Alamos National Laboratory (LANL)            | 26                     | Biosciences, Environmental Health & Safety   |

Table 2.1. (continued)

| Laboratory                                   | Number of Participants | Research Areas Represented                                       |
|--|------------------------|--|
| National Renewable Energy Laboratory (NREL)  | 8                      | Chemical Biosciences, ESH&Q, National Bioenergy<br>Center        |
| Oak Ridge National Laboratory (ORNL)         | 19                     | Biosciences, National Security, Systems Biology                  |
| Pacific Northwest National Laboratory (PNNL) | 15                     | Biosciences, Environmental Health & Safety,<br>National Security |
| Sandia National Laboratories (SNL)           | 6                      | Biosystems Research, Health & Safety                             |

#### 2.2 Survey

Following the workshops, it was necessary to analyze the initial impact of the training on scientists in the national laboratories. It was also necessary to determine sustainable and low-cost mechanisms for promoting education, responsibility, and self-regulation in that community and to explore mechanisms for extending key findings and lessons learned from the workshops to other national and international audiences.

Feedback was gathered through a confidential web-based survey and via focus groups. The survey included 35 questions and took approximately 20 minutes to complete. It was designed to collect information regarding retention from the workshop, ongoing discussions, alterations in behavior and consideration of risk. The survey was sent to 202 individuals who had participated in or helped coordinate the training workshops. Of these, 29 were returned as undeliverable. Survey recipients were also encouraged to forward the survey to their colleagues who may not have received it. In total, 49 individuals initiated the survey; 47 completed it. Of these, 27 (57%) had participated in one of the 2006 Outreach and Education Training Workshops on the Biological Weapons Convention, Dual-Use in the Life Sciences, and Codes of Conduct.

The relatively small sample size meant that survey responses were often not statistically significant; however, in combination with focus group responses, the survey provided anecdotal insight. Initial survey recipients were drawn from a pool of individuals originally selected for their work in basic life science, related research or other areas. Final participants included individuals working in a wide variety of disciplines, ranging from biotechnology to physics to risk analysis. Most were senior research scientists or managers. Therefore, the survey population was not necessarily equally representative of the work force at a particular national laboratory, but skewed toward more experienced scientists with some training and/or background in the issue of dual-use research in the life sciences.

#### 2.3 Focus Groups

During follow-up conferences with subsets of participants (particularly IBC chairs) from the workshops, organizers would:

• Communicate and discuss key findings from workshops, gather any additional feedback from laboratory points of contact (POCs), and discuss the survey results;

- Evaluate whether the type and amount of information presented in the workshops effectively raised education and awareness, and address any gaps (e.g., insufficient information, educational format not sustainable):
- Identify the best options for developing a sustainable, low-cost, educational mechanism that could potentially be deployed and sustained at each laboratory.

For the focus groups, an interview protocol was developed to improve understanding of key issues. A follow-up e-mail invited individuals to interview who participated in the 2006 training and other points of contact at each of the national laboratories (N=202). Of these invitations, 29 were returned as undeliverable. Additional follow-up e-mails were sent to POCs at each laboratory to encourage participation. Separate interviews were conducted with three groups of individuals to evaluate the degree of consensus and differences within each functional group.

These groups were divided into 1) individuals who manage groups of scientists (Managers), 2) individuals who spend a significant portion of their time on bench-level research (Scientists), and 3) representatives of IBCs.<sup>3</sup> There was some overlap among these groups given their multiple roles; for example, most managers were also scientists, although they spent little time doing bench-level research. In addition, IBC members usually wear other hats in their organization. Several individuals fit the criteria for more than one group.

Each group was offered a choice of times, and the date and time preferred for the majority of individual participants was selected for each group. There were five participants in each focus group, with a total of eight laboratories participating. In addition, comments provided by three individuals who were not available to attend the IBC focus group were integrated into the analysis. Table 2.2 summarizes the final focus group participation.

**Table 2.2**. Focus Group Participation

| Focus Group Type    | Number of Participants | Laboratories Represented |
|---------------------|------------------------|--------------------------|
| Scientists          | 5                      | BNL, LANL, ORNL, PNNL    |
| Managers            | 5                      | INL, LANL, NREL, PNNL    |
| IBC Representatives | 5                      | LBNL, LANL, ORNL, SNL    |
| Other               | 3                      | PNNL                     |

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<sup>&</sup>lt;sup>3</sup> This group was also open to representatives of Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs).

#### 3.0 Results and Discussion

These project findings assess the current level of scientist awareness of dual-use risk and the perceived need for increased awareness and/or training; recommendations for the format and delivery of training materials; and questions and concerns raised by participants regarding dual-use guidelines, education and awareness training, and codes of conduct.

#### 3.1 Workshop Series: Key Findings and Lessons Learned

Workshops were designed to promote feedback on the material presented and to generate discussion and awareness. Workshops used a "train-the-trainer" model; participants were asked to communicate relevant information to their colleagues in appropriate venues following the workshops, such as IBC meetings. The workshops were not designed as a sustainable mechanism for either communication or education.

However, one premise of this workshop series was that introducing individuals at the national laboratories to these topics would lay the groundwork for future educational efforts. Following the initial series of workshops, several laboratories noted that as a result of the workshop they had initiated discussions regarding the BWC, individual responsibility, and codes of conduct in their own IBC meetings. Workshop findings included the following:

- 1. Such training is greatly needed in the national laboratory complex; however, further testing and quantifying the impact of the workshops will be necessary to establish a path forward.
- 2. IBCs are the most likely candidates for implementing any guidelines developed regarding dual-use. It is still unclear who would be the appropriate owner and/or implementer of a code of conduct. A key concern is the potential level and availability of funding to support these efforts.
- 3. Scientists did not feel that existing code of conduct drafts were onerous, but were concerned that the implementation process might amplify current requirements unnecessarily. They were also concerned about potential repercussions of an unenforceable code, and noted that personnel reliability might be an appropriate enforcement mechanism.
- 4. Scientists felt that codes need to be driven from the bottom up; scientist participation in development of the code was seen as critical in gaining support and eventual buy-in.
- 5. Communication and perception will be important in developing a culture of responsibility. It was reported in several workshops that the phrase "code of conduct" implied that scientists were engaged in inappropriate behavior or that a situation already existed in which misconduct needed to be addressed. Therefore, the term "code of ethics" was deemed to be more appropriate.
- Scientists were very appreciative about receiving information regarding proliferation concerns as well
  as advance communication on pending guidelines. The participants expect future communications
  and updates.
- 7. Lack of education in this area is a widespread problem in the life sciences. Sustained communication and self-regulation are needed not only in the national laboratories, but also in universities, industry, and other organizations.

Overall, it was evident from the discussions that the workshop series improved awareness of the BWC and international nonproliferation regimes, the national legal and political framework for biological weapons nonproliferation, and the proliferation concerns and potential proliferation pathways associated with work in the life sciences. Participants noted that this improved their ability to understand the purpose of and strengthen their ability to respond to nonproliferation norms and requirements, as established in BWC Article IV, UNSCR 1540, and other obligations.

Scientists indicated that self-regulation of the scientific community through mechanisms such as education, awareness, and codes of conduct would be more effective than government regulation at achieving compliance with BWC and other nonproliferation guidelines, while mitigating negative impacts on the progress of life science. Scientists concurred that education is a critical first step toward this goal, but emphasized that communication and education must be widespread and sustained to be effective.

Some concern was expressed regarding the potential impact of "unfunded mandates" on scientists and their research; however, there was recognition that biological weapons nonproliferation, BWC obligations, dual-use technology, and codes of conduct are critical issues affecting scientific research and the effectiveness of biological weapons nonproliferation measures. Hence, the scientists accepted the importance of addressing these issues proactively, and overall they supported the use of education and outreach to foster a culture of responsibility and awareness.

#### 3.2 Perspectives on Current Developments

Most scientists felt a moral obligation to "do no harm" and conduct research with the best of intentions. There was concern that security oversight could morph into censorship, and that additional legislation and regulation would hamper scientific progress. Participants noted the importance of openness and transparency, and indicated that restrictions on the dissemination of information would only discourage scientific research. In general, scientists were concerned that enforceable guidelines would constrain scientific research without significantly improving biosecurity. Focus group participants believed that mandated guidelines and codes of conduct related to dual-use and biosecurity issues in the life sciences would be overly restrictive, burdensome, and unnecessary. They thought voluntary standards could add needed clarity in this area and help raise awareness, provided they did not evolve into mandatory regulations.

Considerable discussion occurred on the dual-use guidelines and code of conduct being drafted by the NSABB. Participants recognized that if such regulations or guidelines were enacted, the laboratories would have to respond and comply. New guidelines or future regulations would be a driver of awareness, causing scientists who have not been concerned about these issues to take notice. In order to assess fully the future implications, additional guidance would be needed from NSABB, the National Institutes of Health (NIH) and DOE regarding implementation of a code of conduct and/or guidelines. Workshop participants noted that proactive early engagement facilitates cultural change and would give scientists a voice and ownership in the awareness-raising process.

#### 3.3 Increasing the Awareness of Dual-Use Risk

#### 3.3.1 Impact of Pilot Training Workshops

Focus group participants were fairly evenly split between those who had observed an increase in awareness of dual-use in their laboratory since the training versus those who had not seen a change in that timeframe. Factors cited most often as drivers for initial and increased awareness included new or emerging guidelines addressing dual-use research, personal reading or research, and the 2006 Outreach and Education Training provided by PNNL.

Although a level of increased awareness was observed, information obtained by the survey and focus groups showed only subtle changes in actual behavior. Most changes related to *how* information is disseminated through personal communication, conference presentations, or modification of a manuscript; rather than preventing collaboration and particular research, or discouraging the provision of any information at all. The same set of factors that promoted awareness (new or emerging guidelines, personal reading, and the 2006 training) were most often cited as contributing to behavioral change.

#### 3.3.2 Need for Training

Focus group participants had mixed perceptions of the need for additional awareness and/or training—that is, awareness beyond the current level of most scientists. IBC members and managers generally saw value in additional awareness for most scientists. Scientists themselves had more mixed views; some thought that heightened awareness could be valuable for those who do not consider dual-use on a daily basis. Others thought that additional awareness or formal training is not needed, and that sufficient information and protections are available to those who need them.

However, statements indicating no need for increased training were usually accompanied by concerns about burdensome regulations or the impact on research. One possibility is that some scientists resist the idea of training on dual-use not because it is unnecessary, but because it seems to question their scientific judgment and is an administrative task requiring additional time. Although subtle, the increased awareness and behavioral changes from the workshops indicate that despite the basic safety and security measures in place at national laboratories, there is value to providing additional education related to biosecurity and assessment of dual-use risk.

Participants also saw that life science work is becoming increasingly interdisciplinary. In addition to experimental biologists, additional awareness of dual-use concerns may be needed by scientists in other areas, such as mathematical modelers and physical modelers, material scientists, and those working in nanotechnology. Other potential beneficiaries of increased awareness included IBC members, trainees and interns, Security Officers, Authorized Derivative Classifiers, foreign nationals, and project and program managers. It was broadly noted that university students and researchers could benefit from additional training and awareness of dual-use concerns. Survey respondents thought this would help to reduce security risks. Focus group respondents cited universities as an area to target for training because they are perceived to operate under fewer restrictions than the national laboratories; thus, researchers in these settings were considered to be less aware of these issues. Participants noted that training students early would be helpful as they begin their science careers.

#### 3.4 Awareness: Adding Value

#### 3.4.1 Instilling Awareness in Scientific Organizations

The primary impacts of this education were not changes in research topics or publication strategies, but rather increased awareness and better preparation to equip scientists to manage the risks. A majority of participants in both the survey and the focus groups were aware of biosecurity concerns related to dual-use research in the life sciences, and were at least nominally familiar with existing mechanisms for safety and security, such as the BWC. Scientists acknowledged the risks in almost all types of life science research, and noted the potential for dual-use risk in traditional life sciences, such as experimental biology, as well as in emerging areas of research.<sup>4</sup> However, the assessment results indicated that the level of risk awareness varies across disciplines.

In the absence of clear guidance and consensus in the scientific community about what actually constitutes dual-use research of concern, participants tend to be more concerned about security in circumstances where the potential for dual-use is clear cut (e.g., Select Agent research) and where regulations and protections are already in place. Individuals working with Select Agents or pathogens generally had (or were seen as having) a higher level of awareness of dual-use risks; the same held true for those working in areas such as national security or biodefense. Additionally, the focus group participants consistently expected the greatest awareness of dual-use issues among those conducting research with a perceived "high" risk for dual-use potential, versus those conducting research perceived as lower risk.

Individuals in other disciplines or working at lower levels of biosafety (i.e., BSL2 and below) were generally aware of the potential for dual-use or misuse of research, but were not driven by dual-use considerations in planning and conducting their own work. Reasons for this lower level of awareness generally included a perceived lower level of dual-use potential inherent in the research, and the belief that one cannot guard against all possible risk. Participants also stated that "scientists may be intellectually aware of dual-use issues, but they do not necessarily connect these issues to their research on a day-to-day basis." In these circumstances, scientists tend to see dual-use considerations as only of minor concern; greater importance is placed on furthering science and sharing research results.

Across focus groups, the lowest general level of awareness was perceived among individuals working in the academic sector, while scientists working in the national laboratories were considered to have a generally high level of awareness. University researchers were also perceived to have generally fewer regulations placed on the type of work they could conduct.

While national laboratory scientists considered their overall level of awareness to be higher than at academic and commercial organizations, there was still a significant gap in national laboratory scientists' perceived versus actual awareness of dual-use risk. Many scientists felt dual-use risks were adequately addressed by existing safety practices, legal guidelines, and client requirements. Others countered that while many of these measures address biosafety, they are not designed to address a broader spectrum of biosecurity concerns. This gap in awareness may result from a general lack of awareness, a failure to

<sup>&</sup>lt;sup>4</sup> Disciplines that were specifically suggested included mathematical and physical modeling, materials science, and nanotechnology.

distinguish between biosafety and biosecurity concerns, or a general reluctance on the part of the scientific community to acknowledge additional security-related concerns.

#### 3.4.2 Bringing Awareness to Project Planning

Focus group participants believed there is a "shared responsibility" for safety and security. In the national laboratory complex, the project Principal Investigator (PI), program managers and line managers, IBC, biosafety officer, Institutional Review Board (IRB), and Authorized Derivative Classifier (ADC) were all considered to have some responsibility for safety and security of research. Participants noted that the PI develops research directions and considers safety, security, and risk; managers review and approve proposals; IBCs and IRBs review legal and regulatory requirements as well as safety and security guidelines; and ADCs consider classification issues. Participants referred to this as a "defense-in-depth system" for reviewing projects, which is most effective when there is a widespread understanding of dualuse risk by all reviewers.

Among the focus group participants, managers indicated that the PI is responsible for understanding dual-use potential in the project and modifying experiments to mitigate the potential risk. Scientists considered that their institutions have a responsibility to set up clear policies and procedures to assist them in understanding guidelines for pursuing research with dual-use potential. The IBC was considered by both scientists and managers to have a significant role in reviewing dual-use work; however, IBCs currently lack formal guidelines for reviewing dual-use research (other than Select Agent research). It was mentioned several times that IBCs were waiting for guidance from DOE in this regard, although participants were generally opposed to implementing new regulations or formal requirements that would impose additional restrictions.<sup>5</sup>

Overall, most participants believed their institutions have adequate protections in place, and that most researchers are responsible and will not release inappropriate materials. Managers noted that gaps stemming from variability in individual judgment are mitigated by redundant systems for review by individuals and committees – referred to above as "defense-in-depth." However, there is no formal requirement or guidance for dual-use review and no clear line delineating research of concern, making it difficult to identify the risk posed by research. Under these circumstances, reviewers in all areas may need reminders to include dual-use considerations when reviewing current and proposed work, as well as guidance on what constitutes a dual-use concern.

#### 3.4.3 Awareness in Publishing

Extensive discussion surrounded the question of publication and information sharing. It was generally agreed that dual-use should be a consideration when publishing research findings. The scientists' group noted that PIs have a responsibility to use common sense and not disclose inappropriate information, even to other scientists during discussions, at scientific conferences, or via publication in the open literature. It was also suggested that individuals reviewing documents to determine classification might have the responsibility to consider dual-use issues. Additionally, a majority of survey respondents (83%) agreed

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<sup>&</sup>lt;sup>5</sup>Since the time of these discussions, the NSABB has finalized and published guidelines on synthetic biology and recombinant DNA at http://oba.od.nih.gov/rdna\_ibc/ibc\_training.html.

or strongly agreed that scientific journals should have guidelines regarding the publication of dual-use research.

There was, however, disagreement about the scope of such guidelines. Some considered existing guidelines to be adequate, while others thought adequate guidelines are completely lacking in many cases. However, all participants expressed concern that developing and implementing such guidelines could have negative impacts. Reasons for this concern included the following:

- Research is happening on an international scale outside the ability of national security systems to constrain it.
- Much potential dual-use research also has beneficial aims.
- It is better to use technological solutions to keep ahead of the risk rather than assume the release of information can be prevented.
- A nuclear model for nonproliferation is inadequate to the life sciences because there are so many
  "gray areas" in life science where there is a potential for misuse, but also the potential for great
  transformational advances like recombinant DNA technology, PCR, genomics and synthetic biology.
- Restricting publication just leads to the duplication of effort by other credible laboratories and wastes
  resources. Someone will do the research somewhere in the world, perhaps in countries that are
  economic competitors with the U.S. or those that don't share U.S. views regarding the significance of
  the biological threat.

#### 3.4.4 Options for Training

A variety of training options were considered by survey and focus group participants. Survey participants preferred web-based training to classroom training or a reference book. Focus group participants did not reach consensus on the type of training format that would be most valuable. The two most frequently recommended formats were web-based training and in-person sessions, such as brown bags. In general, they considered web-based training applicable for all or most staff, especially if content could be tiered based on the type of research being conducted.

Participants noted that some (e.g., those already working with Select Agents) may already have a basic level of awareness, so training should focus on specific topics of interest, such as the BWC, as well as applied examples and case studies. Participants also indicated that in-person sessions would potentially be more valuable for staff that require specialized information (such as IBC members or managers with specific concerns), as these would allow for discussion of emerging issues lacking clear-cut solutions. Potential benefits and drawbacks to each training option were discussed; a detailed description is provided in Table 3.1.

It was considered preferable to have centrally developed content that would be consistent across national laboratories rather than having each laboratory independently develop material. Content developed and delivered by PNNL staff would be acceptable, although support, buy-in, and leadership from each laboratory, as well as from DOE/NNSA, would be important to implementation. In addition, participants noted that content developed by NSABB or NIH would be valuable to IBCs as supplementary guidance on how to address dual-use concerns. In addition, ensuring the consistency of any training

material developed with emerging NIH or other federal guidelines guidance helps staff understand compliance and informs them of discussions regarding dual-use and biosecurity considerations.

 Table 3.1.
 Benefits and Drawbacks for Training Options

| Training<br>Format   | Audience(s)   | Potential Benefits   | Potential Drawbacks  |
|--|---|--|--|
| Incorporated into existing web-based training                          | Introductory/overview information for all relevant staff; content might provide an overview of key topics                           | Easy to incorporate additional information into existing required training; broad reach  | Staff not retaining information; quizzes for comprehension are generally easy to pass; not interactive; if standard training is offered to all staff, not just those in the life sciences, it may not seem relevant                                |
| Stand-alone<br>web-based<br>training<br>module<br>(multiple<br>topics) | New staff; staff<br>needing in-depth<br>knowledge, such as<br>IBC members;<br>multiple topics might<br>allow tiered delivery        | Possibility for more in-depth<br>presentation of information;<br>content can be tailored to<br>different groups; less resource-<br>intensive than sending people to<br>off-site training | Staff not retaining information; quizzes for comprehension are generally easy to pass; if voluntary, people will not complete it; logistic difficulty in knowing who needs which training and which staff have completed training; not interactive |
| DVD<br>presentation  | TBD; scientists that<br>would benefit from<br>walking through a<br>dual-use scenario  | Gaining consensus on the content would be a helpful clarification on what constitutes dual-use; means to engage participants at a deeper intellectual level                              | Similar to web-training, virtual environment may be off-putting and allow for diversion of focus   |
| Brown bag/<br>in-person<br>sessions                                    | Could be targeted to all<br>relevant staff or to<br>specific groups, i.e.,<br>IBC members,<br>managers, ADCs,<br>biosafety officers | Allows for discussion;<br>encourages interaction around<br>dual-use; may be incorporated<br>into existing series of<br>discussions and offered by<br>on-site staff                       | Logistics difficult to coordinate;<br>may not have a broad reach; could<br>create limitations if people with<br>different clearance levels are<br>present  |
| Webinars   | Could be targeted to all relevant staff   | Seen as a good way to present<br>information as well as provide a<br>discussion forum; conducted to<br>geographically dispersed<br>population  | Similar to DVD presentation, virtual environment may be off-putting and allow for diversion of focus   |
| Hands-on<br>training   | Students/interns  | Helps to retain information;<br>responsibility of PI or mentors<br>to conduct; if they learn it as<br>students they are prepared as<br>new researchers                                   | Trainees may lack context for dual-<br>use training because they are<br>focused on methods   |

#### 4.0 Conclusions

Individual scientists have a role in maintaining and promoting the intent of the BWC—that biology will not be exploited to cause harm and that disease will not be used as a weapon. The results of these workshops illustrate that scientists understand the importance of their role and most are willing to embrace it.

The BWC is an agreement between nations, not individuals, yet the intent of the BWC and other international nonproliferation efforts will increasingly rest upon the expertise and judgment of individual scientists. Directly and indirectly, the individual researcher has an obligation to uphold nonproliferation obligations under the BWC, as well as to follow guidance established under the national legal and political framework. Through education and outreach, the United States has the opportunity to enhance its compliance with the BWC by improving individual understanding (and therefore compliance) by scientists with national and international nonproliferation guidelines. The United States can also use this opportunity to set a standard for responsible behavior for the international research community and for States Parties to the BWC.

An important result of the workshops was an improved understanding by DOE scientists of the legal and political framework for biological weapons nonproliferation and an enhanced understanding of the diverse avenues for proliferation posed by research in the life sciences. The workshops also improved DOE scientists' overall ability to respond to nonproliferation norms and requirements, as established in BWC Article IV, UNSCR 1540 and other policies and international agreements. The workshops have clearly shown that education can enhance compliance with biological weapon nonproliferation obligations.

Both the survey and focus group methodologies were effectively used to obtain information about individuals' awareness of dual-use risk following the workshops; their perceptions of the need for training; and their opinions about the roles, responsibilities, and preventive measures related to life sciences research. However, some characteristics and limitations of the study methodology need to be recognized. Specifically:

- The response rates for the survey were low.
- Many participants were selected or self-selected because of specific interest in the subject matter, which may skew results.

This may mean that awareness among the general scientific community is even lower than indicated by the survey and focus groups, that there is a relatively low level of concern regarding biosecurity, or that scientists do not want to engage in conversations about biosecurity (perhaps because of lack of time, concern about development of rules and regulations, uncertainty about applicability to their work, etc.).

Additionally, the focus group participants were selected from among the survey and workshop participants. While the sessions were conducted as three distinct focus groups (for scientists, managers, and IBC representatives), participants often represented multiple categories. For example, IBC representatives were also scientists, and managers were most often scientists as well. Because the survey and the focus groups were all drawn from the same pool of individuals, results were utilized to assess the

overall range of participant reactions, rather than to reflect the separate reactions of the three focus groups. Nonetheless, several critical themes emerged from this study.

There is variable level of awareness on dual-use risk. Understanding of dual-use issues often varies by individual scientific disciplines and activities. Many factors driving higher awareness of dual-use concerns (e.g., work with Select Agents, work with national security clients, participation in oversight committees, etc.) characterized participants of both the survey and focus groups. All participants had some level of awareness, but there were still significant gaps. For example, while many scientists were aware of the basic concept of dual-use risk, they did not consistently consider these risks when designing research or preparing publications. Additionally, because the participant group is not necessarily a representative sample of laboratory awareness, actual institutional awareness may be lower.

Assessing dual-use risk is challenging. In many cases, it is difficult to identify dual-use research of concern and to accurately assess risks posed by that research. While there is potential for misuse in almost all life science research, it is extremely difficult to characterize the potential risks and benefits of conducting that research and publishing results. When the level of risk is unclear, scientists tend to categorize it as minimal and move forward with research and publication. Under these circumstances, additional guidance and clarity regarding dual-use activities of concern is necessary.

Scientists are concerned about the impact of guidelines. There was a general feeling that scientists should act responsibly by evaluating their research for dual-use potential and taking precautions when sharing information unburdened by regulations. Many participants were clearly opposed to the development and implementation of mandatory guidelines that would govern research or research publications; however, some saw value in voluntary guidelines or codes of conduct as awareness-raising tools.

**Despite a lack of time and resources, training is needed**. Most participants indicated that an awareness of dual-use issues and the BWC would engender a stronger culture of security and responsibility, and most participants saw value in future training in this area. However, there is a lack of time and resources for such training, and most scientists would have low motivation to pursue such training independently. Even more than national laboratory scientists, universities were seen as a particular target for training because of the perception that the academic community has a lower awareness of risk and security guidelines related to research in the life sciences and allied disciplines. In addition, targeting universities for training would provide a framework for building and sustaining a culture of bioresponsibility that effectively blends ethics and BWC treaty obligations.

**Develop a culture of responsibility**. Education on dual-use topics should be provided early and continually reinforced. While it might be difficult to quantify the security benefit resulting from education and cultural change, there is significant value to developing a "culture of responsibility" that includes a shared and heightened awareness of security concerns. As one participant noted, "To me, culture change means getting out of that mentality [of only doing what is required] to one where just as a normal course of doing business as a scientist I will consider these issues."

**Engage young scientists**. It is very important to engage young scientists in these topics as early as possible in their education and training to effectively develop a sustainable culture of responsibility. Participants repeatedly stated that it would be valuable to achieve that objective by working with

academic institutions and professional societies, such as the American Society for Microbiology and American Society of Toxicology, to provide training.

Organizations responsible for training in biosecurity and bioresponsibility will need appropriate tools to accomplish their objectives. At the national laboratories, IBCs are currently the central point for biosafety communication, outreach, and training in most settings. Organizations acting as the focal point for outreach and training on biosecurity and dual-use concerns would most likely require additional tools and resources, as well as support and reasonable guidance. The format and efficacy of training tools will likely vary according to the audience.

#### 5.0 Next Steps

During 2006–2007, DOE supported important groundbreaking work in the field of education and awareness regarding the BWC. Moreover, 2007–2008 offered an excellent opportunity to build on that work by collecting and quantifying valuable "lessons learned" that can be shared with others (i.e., other agencies and other countries) attempting to implement similar education and outreach programs. The 2008 Experts Group meeting of the BWC States Parties addressed, among other issues, the "oversight, education, awareness-raising, and adoption and/or development of codes of conduct with the aim to prevent misuse in the context of advances in bio-science and bio-technology research with the potential of use for purposes prohibited by the Convention." <sup>6</sup>

To date, DOE has shared its key findings and lessons learned with the U.S. BWC interagency working group, BWC Experts Group audiences in 2006 and 2008, and at international workshops in Jordan, Uganda, Kyrgyzstan, and Ukraine. To take timely advantage of interest in bilateral or regional cooperation on these topics expressed by countries in Central Asia, Latin America, Africa, Asia, the Middle East and the Caucasus, it is important that DOE continue efforts to find vehicles for sharing the key findings and lessons learned from the workshops to expanded audiences both nationally and internationally, sharing training materials and offering recommendations for a sustainable educational mechanism.

The evaluation of DOE's previous outreach and education efforts indicates that scientists would benefit from 1) increased awareness of dual-use issues, and 2) simple tools and guidelines that could help in an objective assessment of risk. In addition to helping meet U.S. obligations under Articles IV and X of the BWC, developing tools and providing training on biosecurity awareness would enhance international cooperation and promote transparency through technical assistance and capacity building. Possible options for next steps include the following:

- 1. Develop an educational curriculum and training tools for DOE national laboratories using best practices for low-cost, sustainable deployment of these outreach efforts within the national laboratory complex. DOE/NNSA has sponsored the development of some training material (via PNNL); some training material has also been developed by other organizations. However, development of additional material is needed to provide effective training that targets varying levels of individual understanding. For example, case studies and concrete examples are needed to clarify what is meant by "dual-use" in the life sciences. Additionally, biosecurity and dual-use concerns should be framed in the context of broader issues, such as infectious disease surveillance, public health infrastructure and effective countermeasures, to make these issues more relevant to ongoing research. Material should also be packaged and structured so it can be adapted to a variety of training options (discussed in Section 3.4.4) and meet most effectively the needs of different audiences.
- 2. Collaborate with other organizations in development of training material. Other national and international bodies are developing training materials, some of which were used in the initial outreach and education workshops. Coordinating curriculum development efforts could substantially reduce the effort and cost of this effort, as well as improve the quality of training materials both for the curriculum in national laboratories as well as other organizations. These other organizations include the Federation of American Scientists (FAS), the American Association for the Advancement of Science (AAAS), the National Scientific Advisory Board for Biosecurity (NSABB) and Non-

Governmental Organizations (NGOs). The DOE/NNSA education and outreach effort has been unique in having actually provided dual-use risk training linked to the BWC for a large group of laboratory scientists. Sharing best practices in implementation could provide valuable input to other organizations.

3. Organize and/or participate in training/workshops. The curriculum developed through the education and outreach work, as well as the lessons learned about how to implement, develop, and foster a culture of bioresponsibility that integrates ethics and compliance, would be valuable to audiences beyond those found in the national laboratory complex. It is important for DOE to actively seek opportunities to remain engaged in the growing dialogue related to raising awareness. Organizing and holding seminars, collaborating with other organizations to plan workshops, or participating in thematic workshops planned by others would be effective ways to expose other audiences to this message, educational materials and lessons learned, particularly audiences in academic centers, international collaborators, NGOs and those countries interested in technical cooperation with the United States.

# Appendix A Quantitative Analysis Report

# **Education and Outreach in the Life Sciences Quantitative Analysis Report**

October 2008

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#### 1. Introduction

Rapid developments in biotechnology and the life sciences bring significant benefits but also create new security challenges. In recent years, members of the scientific and security policy communities have raised concerns about the potential for misuse of knowledge, tools, and techniques for purposes of bioterrorism. Such research is sometimes called "dual-use" research because, although the research is intended for beneficial purposes only, it could be misapplied. The role of scientists, institutions, scientific societies, and the government is critical in fostering an environment that enhances both the scientific enterprise and national security.

In 2004, the U.S. government established the National Science Advisory Board on Biosecurity (NSABB) under the auspices of the National Institutes of Health (NIH) to contemplate the possibility and impact of greater oversight for life sciences research to prevent or mitigate deliberate misuse. Similarly, the U.S. Department of Energy (DOE) is considering how to respond to emerging issues of concern related to dual-use. Other federal agencies are planning to issue further guidelines and are considering additional policies regarding responsible scientific research. Discussion sessions on this topic were also conducted by Pacific Northwest National Laboratory (PNNL) for DOE's Office of International Regimes and Agreements (NA-243) at ten of the national laboratories in Fall 2006.

The DOE's National Nuclear Security Agency (NNSA) asked PNNL to consider the role of individual scientists in upholding safety and security. The views of scientists were identified as being a critical component of this policy process. Therefore, scientists, managers, and representatives of Institutional Biosafety Committees (IBCs) at the national labs were invited to participate in a brief survey that was designed to:

- Evaluate the function of the 2006 outreach and education seminars that were conducted by the U.S. DOE;
- Assess the opinions of scientists about potential future mechanisms to address dual-use concerns in the life sciences community;
- Gather data on scientists' attitudes toward potential security risks from agricultural, public health, and biomedical research;
- Give scientists a voice in the policy-making process.

In addition, three focus groups were conducted with scientists, managers, and IBC representatives to discuss some of the questions related to education, outreach, and codes of conduct in more detail and gather further input on biosecurity and dual-use awareness at the laboratories. The overall purpose of this process was to identify concerns related to these topics and to gather suggestions for creating an environment where both the scientific enterprise and national security are enhanced.

The information gathered through the survey and focus groups will be instrumental in informing the U.S. position at the Biological Weapons Convention (BWC) Experts' Group meeting in August 2008, as well as moving toward a sustainable mechanism for biosecurity education and awareness. It will also help guide DOE action in developing educational tools that will help promote a laboratory culture of responsibility.

This report presents the results from the web survey. The focus group findings are presented in a separate report.

#### 2. Methods

The survey was developed by the PNNL project team in consultation with Centers for Public Health Research and Evaluation researchers. PNNL programmed the web survey using their proprietary websurvey software. The PNNL Project Director distributed the survey by sending e-mail invitations to individuals who participated in the 2006 training and other points of contact at each of the national laboratories (N=202). Of these, 173 were delivered and 29 were returned undeliverable. This e-mail introduced the purpose of the survey and invited individuals to participate by clicking on a link. Individuals were also encouraged to forward the survey link to others who might be interested in participating. Several follow-up e-mails were sent to the entire sample encouraging participation. Forty-nine (49) individuals initiated the web survey. Two cases were removed due to incomplete surveys, leaving a final sample of 47 respondents. A copy of the survey instrument used is included in Appendix A1; answers to the survey are in Appendix A2.

# 3. Sample Description

Survey respondents represented several labs, with the majority (58%) located in Pacific Northwest, Oak Ridge, and Sandia. Most of the respondents (68%) have doctorate degrees or the equivalent. The year in which the highest degree was awarded ranges from 1969 to 2007, with 1985 as the median year. Respondents work or study in a variety of scientific disciplines, including Biodefense (15%), Biotechnology (13%), and Molecular Biology (13%). Senior Research Scientists make up the largest role group (43%), with others representing Program/Project Managers (19%), Mid-Level Research Scientists (17%), Laboratory Managers (10%), and Others (12%), including International Review Board (IRB) or IBC Chairs or Members, Biological Safety Officer, Research Ops Manager, and Post Doc. A majority of respondents conduct or manage research in the life sciences and contribute to journal articles. Thirty-eight percent (38%) have also served on an IBC. None of the respondents have served on an IRB.

# 4. Key Findings

In this section, we highlight the key findings for each section of the survey. Specific results for each research question are presented in Section 5 (Survey Results).

# 4.1 Biosafety Awareness and Experience (Questions 4-10)

One-half of the respondents consider that they are currently conducting or managing research with dual-use potential, and 57% have had experience with Select Agents. Only a small percentage (4%) consider that their work would fall under the 7 categories identified by the NSABB for special review (i.e., experiments "of dual-use concern"). Most respondents (89%) consider that they are familiar with BWC; however, only 63% are familiar with the individual provisions for biosafety and biosecurity, and only 64% are familiar with the BWC introducing the concept of individual responsibility.

# 4.2 2006 Outreach and Education Training (Questions 11-24)

More than one-half of the respondents (57%) participated in the 2006 Outreach and Education Training. At least 44% of the respondents found the trainings to be relatively effective in terms of training materials, venue, and presentation. Training materials were considered to be less than effective by 29% of the attendees, the presentations were found to be less than effective by 22% of attendees.

Web-based training is the preferred training type, with 81% of respondents choosing that option when asked to choose between web-based, classroom training, or reference book for recommended or mandatory training on the BWC. Six percent of participants indicated that no training was necessary.

Few have made changes in research conduct or management in the past 2 years as a result of dual-use research concerns. A small portion of scientists did change the focus of a research project, modify a paper or presentation, or limit conversation and/or collaboration with other scientists. Although most scientists have not made significant modifications in how they undertake research, over 68% participated in discussions regarding dual-use issues with management, researchers, and IBC participants.

Most scientists indicated training on these subjects should be widespread, and include senior and junior scientists, program, project, and laboratory managers, and IBC/IRB chairs and members.

## 4.3 Publication and Journal Review (Questions 26-34)

While most respondents have reviewed manuscripts for a journal, few (7%) have reviewed a manuscript that they felt contained knowledge, tools, or techniques that could pose a threat to national security. Although a relatively large proportion did not know whether journals required reviewers to evaluate manuscripts for potential dual-use information or whether the professional science societies of which they are members have codes of conduct for dual-use research. Also, most agree that journals should have guidelines and that professional science societies should have codes of conduct regarding dual-use research.

### 4.4 Minimizing Threat to National Security (Questions 38-61)

The next sections discuss findings for the area of the survey that asked respondents' opinions on possible actions that could be taken to minimize the potential threat to national security that may be posed by knowledge, tools, or techniques from dual-use research.

#### 4.4.1 Role and Responsibilities of Scientists (Questions 38-42)

Most believe that scientists taking responsibility for evaluating dual-use potential in their research and assuring institutions of this assessment would help reduce the potential threat to national security. Respondents strongly indicated that principal investigators should conduct an initial evaluation of the dual-use potential of their work; agreement was less strong that scientists should provide formal assurance to their institution that they are assessing their work for dual-use potential.

There is some disagreement among respondents regarding whether scientists should be required to take a Hippocratic-like oath or to obtain certification to conduct dual-use research. Although 28% of respondents believe that providing greater federal oversight would minimize potential threat, the majority of respondents had no opinion about this option or disagreed.

### 4.4.2 Access to Agents and Equipment (Questions 45-46)

A majority of respondents (66%) indicated that requiring licensure of biological equipment would not minimize potential threat to national security, but there was disagreement about whether greater restrictions on agents/toxins would make a difference. Almost one-half (45%) agreed that the restrictions would minimize risk, and nearly the same number (43%) disagreed. This disagreement does not vary by role, laboratory, or year of degree—members within groups disagreed with each other.

#### 4.4.3 Research Findings (Questions 49-52)

Actions related to Research Findings received mixed support. One of the consistent findings is that nearly 20% of respondents neither agreed nor disagreed with the proposed restrictions on research findings. Nearly equal proportions agreed versus disagreed with statements regarding placing restrictions on disclosure through personal communication, alterations prior to publication or presentation, and restrictions on publication of findings. Forty-six percent (46%) of respondents agreed that classifying research findings would minimize the potential threat to national security compared to 31% who disagreed.

### 4.4.4 Training (Questions 55-57)

Respondents generally agreed that PIs providing training for laboratory staff, students, and visiting scientists would minimize potential threat to national security. Having institutions provide mandatory training for scientists regarding dual-use life sciences research also received support, although less strongly than PIs providing recommended training. There was very strong support that training be given to university and college students.

#### 4.4.5 Review and Funding (Questions 60-61)

Forty-seven percent (47%) of respondents agreed that the review of all grant proposals by entities like an IBC prior to submission would minimize risk, while 43% disagreed. The majority of respondents (62%) agreed that potential threat would be minimized if funding agencies required grantee applicants to attest that dual-use implications have been considered.

## 4.5. Opinions about Bioterrorism and Dual-Use Research (Questions 64-73)

When asked about the level of existing threat of bioterrorism, respondents indicated that there was an average 57% chance that an act of bioterrorism would occur "in the world" in the next five years and an average 37% chance that one would occur in the United States. One-half of the respondents said that there was up to a 25% chance that dual-use research will facilitate acts of bioterrorism.

Forty-three percent (43%) of respondents did not agree with the statement that funding agencies would be less likely to fund grant proposals if the proposed research had dual-use potential, and 30% were neutral or had no opinion. Respondents believe that the most likely ways to obtain potentially sufficient information to deliberately create a harmful biological agent are via scientific journal articles and the Internet. There was some disagreement about whether presentations at conferences or meetings or personal communications could provide sufficient information.

### **5** Conclusions and Recommendations

Respondents indicate that they are generally aware of the risks associated with research having dual-use potential. More than half had participated in the PNNL pilot training on the BWC, dual-use risks, and codes of conduct. Additionally, some had become aware of these issues through emerging guidelines or personal reading. Just one-half are currently conducting or managing research with dual-use potential and slightly more have been involved with Select Agents, but most indicated that they are familiar with the Biological Weapons Convention. Many also indicated that they are familiar with the associated provisions and articles.

Although many do not know to what extent scientific journals and professional societies have requirements or codes of conduct related to dual-use potential, most agree that journals and professional societies should have these in place. There was general agreement that training on the BWC, dual-use potential, and codes of conduct by project PIs would help minimize risk. There was agreement, though less strongly, that institutions should provide mandatory training on these topics. There was strong agreement that colleges and universities should offer this training.

The level of threat of bioterrorist acts is considered to be relatively high. However, respondents believe that the chance that an act of bioterrorism would be facilitated by dual-use life sciences research is only about 25%. Of the possible means of communication that could provide sufficient information for an individual with college-level life science training to deliberately create a harmful biological agent, the internet and scientific journals were considered to be the most likely means.

One of the ways in which respondents believe risk to national security could be minimized is through training. Respondents recommended that training that covers scientist obligations under the BWC, dualuse risks of research, and codes of conduct should be provided to nearly all groups, including scientists of all levels, program/project/laboratory managers, and IBC/IRB chairs and members. There was also support for training for research associates and technicians. Most respondents agreed that the potential threat to national security would be minimized if principal investigators trained laboratory staff, students, and visiting professors about dual-use research and if university and college students received education about the potential misuse of life sciences research.

Over one-half of the respondents participated in the 2006 Outreach and Education Training on the Biological Weapons Convention, Dual-Use in the Life Sciences, and Codes of Conduct given by DOE. On a scale of 1-5, with 5 being "Very Effective," at least 70% of respondents rated the training from 3-5 for training materials, venue, and presentation. Of the three aspects of training, respondents rated the training materials least favorable, with 29% indicating that the training materials were "Not effective." Respondents prefer "web-based" training to "classroom training" or "reference book" training. A combination of training options may be ideal. Some respondents referred to the importance of live discussion with trainers and the usefulness of having reference books in combination with web-based training. A self-paced web-based training with reference handbook and scheduled LiveMeeting or chat session might be an effective combination.

In addition to participating in training discussions regarding dual-use research or codes of conduct, respondents demonstrate awareness of the related issues as a result of new guidelines addressing dual-use research and personal reading or research. Most have not made any changes in the past 2 years in how they conduct or manage research because of concerns that their research may be misused for bioterrorism.

Of those who have made changes, some have done so by limiting conversations about their research. Scientists' concerns about the dual-use potential of their work did not seem to deter them from conducting the research, collaborating, submitting manuscripts, or presenting research. It seems indicated that the value of education is not effected through scientists' changing research topics or publication strategies, but rather, through raising awareness, and better equipping scientists to manage risk.

Respondents believe that scientists should have responsibility for minimizing potential threat to national security by conducting evaluations of dual-use potential of their own research and providing assurance to their institutions or funding agencies that this assessment has been made. Overall, respondents do not think that requiring scientists to take an oath to carry out research responsibly, or requiring researchers to be certified, or providing greater Federal oversight of dual-use research would lead to less risk to national security. Not all believe that providing mandatory training for scientists regarding dual-use life sciences research would minimize risk—24% indicated a neutral response to this action, and 26% disagreed.

Putting restrictions on access to biological agents, and on dissemination of research, received mixed support. Most disagree that requiring licensure of certain biological equipment often used in life science research would minimize potential threat to national security, but respondents' opinions vary when evaluating actions involving greater restrictions on access to specific biological agents/toxins or restrictions on publication of findings or disclosure of research details based on dual-use potential. There is some support for classifying research findings on dual-use potential. Comments supplied at the end of the survey indicate that some believe strongly that information with dual-use potential is readily available and that restrictions on the dissemination of information could do more harm by limiting research advances.

The processes of funding research and disseminating research details and findings are considered to be areas worthy of potentially useful restrictions by some, but not by all. There is disagreement about whether having an individual or board (like an IBC) review all life sciences grant proposals with dual-use potential prior to submission will minimize threat to national security. Similarly, there is variable support for actions such as placing restrictions on disclosure through personal communication or publication and altering methods or findings before publication or presentation. It is not clear whether certain groups of respondents were more likely to agree or disagree with these statements. We did find that a larger percentage of 2006 Outreach and Education trainees versus non-trainees agreed that the action "Placing restrictions on disclosure of details about the research or its findings through personal communication" would minimize threat but it is not clear that the difference is significant.

Education about the risks associated with life sciences research with dual-use potential is considered a valuable tool in protecting against acts of bioterrorism. The respondents in this sample support the idea of providing training to scientists, technicians, managers, IBC/IRB members, and students in order to increase awareness about potential security risks associated with life sciences research. Those who participated in the 2006 Outreach and Education Training by the Department of Energy found it to be relatively effective and most would recommend a primarily web-based training to cover topics related to the Biological Weapons Convention, codes of conduct, and dual-use concerns.

Respondents seem to favor self-imposed restrictions and research evaluation as opposed to mandated training/certification, additional board review processes, or government restrictions on access to equipment or oversight of dual-use research. One issue raised in several comments at the end of the survey indicated concern that any restriction or regulation or mandatory guidelines would be "untargeted"

and impact life science research that does not have significant dual-use concerns. They welcome the development of publication guidelines and scientific society codes of conduct regarding dual-use research. However, through comments, scientists also raised concern that any attempt to reduce the risk of bioterrorism through guidelines or regulations would hamper research and limit the dissemination of new knowledge. Additional comments indicated that education and personal accountability are critical to successful biosecurity.

# Appendix A1 Survey Instrument

#### Welcome!

Rapid developments in biotechnology and the life sciences bring significant benefits, but also create new security challenges. In recent years, members of the scientific and security policy communities have raised concerns about the potential for misuse of knowledge, tools and techniques for purposes of bioterrorism. Such research is sometimes called "dual-use" research because, although the research is intended for beneficial purposes only, it could be misapplied. The role of scientists, institutions, scientific societies, and the government is critical in fostering an environment that enhances both the scientific enterprise and national security.

In 2004, the U.S. government established the National Science Advisory Board on Biosecurity (NSABB) under the auspices of the National Institutes of Health to contemplate the possibility and impact of greater oversight for life sciences research to prevent or mitigate deliberate misuse. Similarly, the US Department of Energy (DOE) is considering how to respond to emerging issues of concern related to dual-use. Other Federal agencies are planning to issue further guidelines and considering additional policies regarding responsible scientific research.

Your views are critical in this policy process. It is very important for the government to be aware of and informed by the views of scientists—to hear your concerns and also your suggestions for creating an environment where both the scientific enterprise and national security are enhanced.

The DOE's National Nuclear Security Agency (NNSA) has asked Pacific Northwest National Laboratory (PNNL) to consider the role of individual scientists in upholding safety and security. Therefore, we invite you to participate in this brief survey, which is designed to:

- Evaluate the function of the 2006 outreach and education seminars that were conducted by DOE
- Assess the opinions of scientists about potential future mechanisms to address dual-use concerns in the life sciences community
- Gather data on scientists' attitudes toward potential security risks from agricultural, public health, and biomedical research
- Give scientists a voice in the policy making process.

The survey will take approximately 20 minutes to complete. While the results will be summarized in aggregate, it is possible that combinations of responses to some of the questions in the survey could allow an individual respondent to be identified. Please note that you may skip any question you do not wish to answer. Aggregate survey results will be shared with policy makers and the scientific community.

Thank you for your vital contribution to this important policy process.

| Qι                        | iestions  |
|---------------------------|---|
| Lat<br>Titl               | poratory:   |
| GE                        | ENERAL QUESTIONS  |
| 1.                        | Please note which of the following activities your work scope includes. (Please check all that apply):  |
|                           | <ul> <li>□ Conducting research in the life sciences</li> <li>□ Managing research in the life sciences</li> <li>□ Serving on an Institutional Biosafety Committee (IBC)</li> <li>□ Serving on an Institutional Review Board (IRB)</li> <li>□ Contributing to journal articles</li> </ul>   |
| 2.                        | Do you consider any of the research you currently <u>conduct</u> or <u>manage</u> as having dual-use potential?   |
|                           | ☐ Yes<br>☐ No   |
| 3.                        | Do you now, or have you ever, worked with or managed research using Select Agents?  |
|                           | ☐ Yes ☐ No ☐ Don't know   |
| rese<br>exp<br>(1)<br>(2) | e National Science Advisory Board for Biosecurity (NSABB) has identified a subset of life sciences earch that they believe may be worthwhile but may also need special review. Such research includes periments designed to: enhance the harmful consequences of a biological agent or toxin; disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural tification; |

- (3) confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies;
- (4) increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin;
- (5) alter the host range or tropism of a biological agent or toxin;
- (6) enhance the susceptibility of a host population; and
- (7) generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

|             | 4. Are you currently <u>conducting</u> or <u>managing</u> research which includes any of these seven types of experiments?                                |  |                |                 |               |                   |
|-------------|---|--|----------------|-----------------|---------------|-------------------|
|             | Yes No Don't Know   |  |                |                 |               |                   |
| 5. A        | Are you familiar w  | ith the Biological Wea                         | pons Convent   | ion (BWC)?      |               |                   |
|             | Yes → (Contin<br>No → (Skip to<br>Don't Know →  | Q6)  |                |                 |               |                   |
| a           | . Are you familia Articles?   | ar with the provisions f                       | or biosafety a | and biosecurity | as discussed  | in its individual |
|             | ☐ Yes ☐ No ☐ Don't Kno  | w  |                |                 |               |                   |
|             | lding and promoting   | Article IV of the BWC ng the nonproliferation  |                |                 |               |                   |
| [<br>[<br>[ | Yes No Don't Know   |  |                |                 |               |                   |
| QUE         | STIONS RELAT  | TED TO 2006 OUTRE                              | EACH AND       | EDUCATION       | TRAINING      | }                 |
|             |   | in the 2006 Outreach ain the Life Sciences, ar |                |                 | he Biological | Weapons           |
|             | Yes No → (Skip to   | Question 9)                                    |                |                 |               |                   |
|             | 8. How effective were the following aspects of the training in conveying information on the BWC, codes of conduct, and dual-use and biosecurity concerns? |  |                |                 |               |                   |
|             | Not effective at all Very effective   |  |                |                 |               |                   |
| Tra         | ining materials   | 1  | 2              | 3               | 4             | 5                 |
| Ven         |   | 1  | 2              | 3               | 4             | 5                 |
| Pres        | sentation   | 1  | 2              | 3               | 4             | 5                 |

| 9. If a recommended or mandatory training on the BWC and dual-use research we choice of web-based training, on-site classroom training, or as a reference handbook choose?                                    |         |          |     |
|---|---------|----------|-----|
| <ul> <li>□ Web-based</li> <li>□ Classroom Training</li> <li>□ Reference Book</li> <li>□ Other (Please Specify)</li> </ul>   |         |          |     |
| 10. Have you made any changes in the past 2 years in how you conduct or manage concerns that knowledge, tools or techniques from your research might be deliberated facilitate bioterrorism?                  |         |          |     |
|   | Yes     | No       | 1   |
| I decided against conducting a specific research project/experiment   |         |          |     |
| I decided to shift my research away from an area altogether   |         |          |     |
| I decided against seeking funding for a proposed research project   |         |          |     |
| I decided against collaborating with particular scientists, postdocs, students, etc.  |         |          |     |
| I limited my conversations about my research  |         |          |     |
| I decided against submitting a manuscript to a journal  |         |          |     |
| I modified a manuscript   |         |          |     |
| I decided against presenting research at a conference   |         |          |     |
| I modified a conference presentation  |         |          |     |
| (If no to all of the items in Question 10, skip to question 12)  11. What contributed to this change in how you conduct or manage research? (Ple apply)   | ase che | ck all t | hat |
| <ul> <li>□ Training conducted by PNNL</li> <li>□ Training provided by another laboratory or organization (If yes, please spe</li> <li>□ Other related training or education (If yes, please specify</li></ul> |         |          | _)  |
| 12. Have you participated in any discussions regarding dual-use research or codes management, researcher or Institutional Biosafety Committee (IBC) participants?  ☐ Yes ☐ No → (Skip to Question 14)         | of cond | luct wit | :h  |

| 13. If yes, were these discussions a result of any or all of the fo  | llowing  | g?     |                            |
|--|----------|--------|----------------------------|
|  | Yes      | No     |                            |
| Training conducted by PNNL   |          |        |                            |
| Training conducted by another laboratory or organization   |          |        |                            |
| Other related training or organization   |          |        |                            |
| New or emerging guidelines addressing dual-use research  |          |        |                            |
| Personal reading or research   |          |        |                            |
| 14. Who should participate in training that covers scientist oblives research, and codes of conduct? (Please check all that apply)  Senior Research Scientists  Mid-level Research Scientists  Junior Scientists  Program/Project Managers  Laboratory Managers  IBC/IRB chairs and members  Research associates/technicians  Other (Please Specify)  There is no need for such training | gations  | under  | the BWC, dual-use risks    |
| QUESTIONS RELATED TO PUBLICATION AND JOUR  15. Have you ever reviewed a manuscript for a journal?  | NAL R    | EVIEV  | W                          |
| ☐ Yes ☐ No →(skip to Q18)  |          |        |                            |
| 16. Have you ever felt that a manuscript you were reviewing contact that could pose a threat to national security?   | ontaineo | d know | ledge, tools or techniques |
| <ul><li>☐ Yes</li><li>☐ No →(skip to Q18)</li></ul>  |          |        |                            |
| 17. Have you ever contacted an editor to raise this concern?   |          |        |                            |
| ☐ Yes<br>☐ No  |          |        |                            |

| None of the journals  □ None of the journals □ Don't know  Please indicate your opinion about the following          | ootential?        |             | duate whether          | manuscript  | s include            |
|--|-------------------|-------------|------------------------|-------------|----------------------|
|  | Strongly<br>Agree | Agree       | Neutral/<br>No Opinion | Disagree    | Strongly<br>Disagree |
| 19. Scientific journals should have guidelines regarding publication of dual-use research.                           |                   |             |                        |             |                      |
| 20. Professional science societies should have codes for the responsible conduct of dual-use life sciences research. |                   |             |                        |             |                      |
| 21. Are you a member of any professional sciendual-use research?  Yes (Please Specify)  No Don't know                | ace societies     | s that have | e codes of respo       | onsible con | duct for             |

Next we would like to ask your opinion on possible actions that could be taken to minimize the potential threat to national security that may be posed by knowledge, tools, or techniques from dual-use research.

For each item under Role and Responsibilities of Scientists, please indicate whether you think this action would minimize the potential threat to national security.

| 22. | Role and Responsibilities of Scientists  | Strongly<br>Agree | Agree | Neutral/<br>No Opinion | Disagree | Strongly<br>Disagree |
|-----|--|-------------------|-------|------------------------|----------|----------------------|
| a.  | Principal investigators conducting an initial evaluation of the dual-use potential of their life sciences research.  |                   |       |                        |          |                      |
| b.  | Scientists providing formal assurance to<br>their institution that they are assessing their<br>work for dual-use potential (e.g. such as<br>following dual-use recommendations or<br>guidelines)   |                   |       |                        |          |                      |
| c.  | Requiring scientists conducting or managing research to take an oath, similar to medicine's Hippocratic Oath, to carry out research responsibly and guard against deliberate misuse of the knowledge, tools or techniques of dual-use research |                   |       |                        |          |                      |
| d.  | Requiring certification for researchers conducting some dual-use research.   |                   |       |                        |          |                      |
| e.  | Providing greater federal oversight of dualuse research.   |                   |       |                        |          |                      |

For each item under Access to Agents and Equipment, please indicate whether you think this action would minimize the potential threat to national security.

| 23 | . Access to Agents and Equipment  | Strongly<br>Agree | Agree | Neutral/<br>No Opinion | Disagree | Strongly<br>Disagree |
|----|---|-------------------|-------|------------------------|----------|----------------------|
| a. | Placing greater restrictions on access to specific biological agents or toxins.                     |                   |       |                        |          |                      |
| b. | Requiring licensure of certain biological equipment that is commonly used in life science research. |                   |       |                        |          |                      |

For each item under Research Findings, please indicate whether you think this action would minimize the potential threat to national security.

| 24. | Research Findings  | Strongly<br>Agree | Agree | Neutral/<br>No Opinion | Disagree | Strongly<br>Disagree |
|-----|--|-------------------|-------|------------------------|----------|----------------------|
| a.  | Placing restrictions on disclosure of details about the research or its findings through personal communication. |                   |       |                        |          |                      |
| b.  | Altering or removing certain experimental methods or findings prior to publication or presentation.              |                   |       |                        |          |                      |
| c.  | Placing restrictions on publication of findings based on dual-use potential.                                     |                   |       |                        |          |                      |
| d.  | Classifying research findings on dual-use potential.   |                   |       |                        |          |                      |

For each item under Training, please indicate whether you think this action would minimize the potential threat to national security.

| 25 | . <u>Training</u>   | Strongly<br>Agree | Agree | Neutral/<br>No Opinion | Disagree | Strongly<br>Disagree |
|----|---|-------------------|-------|------------------------|----------|----------------------|
| a. | Principal investigators providing training to lab staff, students and visiting scientists about dual-use research including policies and practices to minimize the potential for misuse of information from their research.                 |                   |       |                        |          |                      |
| b. | University and college students receiving educational lectures and materials on dualuse life sciences research including the potential that knowledge, tools and techniques of such research that could pose a threat to national security. |                   |       |                        |          |                      |
| c. | Institutions providing mandatory training for scientists regarding dual-use life sciences research.   |                   |       |                        |          |                      |

For each item under Review and Funding, please indicate whether you think this action would minimize the potential threat to national security.

| 26. Review and Funding  | Strongly<br>Agree | Agree              | Neutral/<br>No Opinion | Disagree         | Strongly<br>Disagree |
|---|-------------------|--------------------|------------------------|------------------|----------------------|
| a. Reviewing all grant proposals for life sciences research with dual-use potential by an appropriate individual or board (such as an IBC) at a researcher's institution prior to submission for funding. |                   |                    |                        |                  |                      |
| b. Funding agencies requiring grantees to attest on grant applications that they have considered dual-use implications of their proposed research.  |                   |                    |                        |                  |                      |
| Next we are interested in your opinions about to 27. Please indicate your opinion about the following fund grant proposals if the proposed research had   | ing statemen      | nt: Fundir         |                        |                  | likely to            |
| Strongly agree Agree Neutral/No   | opinion           | Disaş<br>C         | gree<br>]              | Strongly di<br>□ | sagree               |
| 28. In your opinion, what is the percent chance (rabioterrorism will occur somewhere in the next five   |                   | n 0% chan          | ce to 100% cha         | ance) that a     | n act of             |
| In the world:% In the United States:%   |                   |                    |                        |                  |                      |
| 29. In your opinion, what is the percent chance (reknowledge, tools or techniques from <u>dual-use life</u> somewhere in the world in the next five years? %  | ~ ~               |                    |                        |                  | rorism               |
| 30. In your opinion, do the following means of coinformation for an individual with college level libiological agent?   |                   |                    |                        |                  |                      |
| Scientific journal articles Presentations at scientific conferences or meetings Personal communications (e.g., e-mail, phone call Internet  | s<br>Is)          | /es<br>□<br>□<br>□ | No  □ □ □ □            | Don't Knov       | w                    |

# And finally, please give us a little information about yourself:

| 31. | Wh | aat is the highest educational degree you have been awarded?   |
|-----|----|--|
|     |    | Bachelor's degree or equivalent (e.g., BS, BA, AB) Master's degree or equivalent (e.g., MS, MA, MBA, etc.) Doctorate or equivalent (e.g., PhD, DSc, EdD, etc.) Other professional degree (e.g., JD, LLB, MD, DDS, DVM, etc.) Joint doctorate and professional degree (e.g. Ph.D. and MD) Other |
| 32. |    | what year was your highest educational degree awarded? YYY)  |
|     |    | nich scientific discipline do you consider your primary area of work or study? (If currently oyed or retired, please select the discipline that most closely matches your last occupation.)  |
|     |    | Agricultural Science Biochemistry Biodefense Biomedical Engineering Biotechnology Botany Cell Biology Ecology Endocrinology/Physiology Genetics Geology/Soil Sciences/Geography Immunology Marine Biology Medicine Microbiology Molecular Biology Neuroscience Pharmacology Zoology Other:     |
| 34. | Wh | nich best describes your current role?   |
|     |    | Senior Research Scientist Mid-level Research Scientist Junior Scientist Program/Project Manager Laboratory Manager Research associate/technician Other (Please Specify)  |

| 35. Do you have any additional comments regarding regulation and oversight of dual-use research you would like federal policy makers to consider?                       |
|---|
|   |
|   |
|   |
|   |
|   |
|   |
|   |
| Thank you very much for taking the time to complete this survey!  It is very important for the U.S. government to be aware of and informed by the views of the nation's |
| scientists — hearing your concerns and your suggestions helps create an environment where both the scientific enterprise and national security are enhanced.            |
| Thank you again.  |

# Appendix A2 Survey Answers

This section presents the survey results in greater detail. Summaries of results are given preceding each question or set of questions. Sample sizes are provided in parentheses.

# **B.1** Laboratory

Respondents were asked to type in the name of the laboratory where they worked. Table 1 shows the distribution of responses. The majority of respondents (58%) are located in the Oak Ridge, Pacific Northwest, and Sandia labs, with most located in the Pacific Northwest (28%).

| Question 1. Laboratory    | % Respondents (N) |  |
|---------------------------|-------------------|--|
| Argonne                   | 4% (2)            |  |
| Brookhaven                | 9% (4)            |  |
| Idaho                     | 6% (3)            |  |
| Lawrence Berkeley         | 6% (3)            |  |
| Los Alamos                | 9% (4)            |  |
| National Renewable Energy | 4% (2)            |  |
| Oak Ridge                 | 15% (7)           |  |
| Pacific Northwest         | 28% (13)          |  |
| Sandia                    | 15% (7)           |  |
| Missing                   | 4% (2)            |  |
| Total                     | 100% (47)         |  |

#### **B.2** Biosafety Awareness and Experience (Questions 4-10)

In the General Questions section of the survey, respondents were asked about experience and awareness of issues related to biosecurity.

**Activities in scope of work**. For the question regarding scope of work, the respondents were asked to check all that applied. Over 60% of respondents conduct or manage research in the life sciences and contribute to journal articles. None serve on an Institutional Review Board, but nearly 40% have served on an Institutional Biosafety Committee.

| Question 3. Activities included in work scope         | % Respondents (N) |      |
|---|-------------------|------|
| Conducting research in the life sciences              | 66%               | (31) |
| Managing research in the life sciences                | 60%               | (28) |
| Serving on an Institutional Biosafety Committee (IBC) | 38%               | (18) |
| Serving on an Institutional Review Board (IRB)        | 0%                | (0)  |
| Contributing to journal articles                      | 62%               | (29) |

**Research with dual-use potential**. One-half of the respondents currently conduct or manage research that has dual-use potential.

| Question 4. Currently conduct or manage research with dual-use potential | % Respondents (N) |  |
|--|-------------------|--|
| Yes  | 50% (23)          |  |
| No   | 50% (23)          |  |
| Total  | 100% (46)         |  |

**Experience with Select Agents**. A majority of respondents (57%) have ever worked with or managed research using Select Agents.

| Question 5. Ever worked or managed research using Select Agents | % Respondents (N) |  |
|---|-------------------|--|
| Yes   | 57% (26)          |  |
| No  | 43% (20)          |  |
| Total   | 100% (46)         |  |

**Research needing special review**. In preparation for Question 7, respondents were presented with a list of seven types of life sciences research that may require special review. This list is shown in the box below.

# Preface to Question 7. Involved in Research that Potentially Needs Special Review

The National Science Advisory Board for Biosecurity (NSABB) has identified a subset of life sciences research that they believe may be worthwhile but may also need special review. Such research includes experiments designed to:

- (1) enhance the harmful consequences of a biological agent or toxin;
- (2) disrupt immunity or the effectiveness of an immunization without clinical and/or agricultural justification;
- (3) confer to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin, or facilitate their ability to evade detection methodologies;
- (4) increase the stability, transmissibility, or the ability to disseminate a biological agent or toxin;
- (5) alter the host range or tropism of a biological agent or toxin;
- (6) enhance the susceptibility of a host population; and
- (7) generate a novel pathogenic agent or toxin, or reconstitute an eradicated or extinct biological agent.

Most of the respondents are not currently conducting or managing research that includes the types of experiments that potentially need special review.

| Question 7. Conducting or managing research that might need special review | % Respondents (N) |      |
|--|-------------------|------|
| Yes  | 4%                | (2)  |
| No   | 89%               | (42) |
| Don't Know   | 6%                | (3)  |
| Total  | 100%              | (47) |

**Familiarity with biological weapons convention**. Questions 8-10 (Tables 7-9) assess the respondents' familiarity with the Biological Weapons Convention and Articles. Nearly all of the respondents are familiar with the BWC (89%) but are less familiar with the provisions for biosafety and biosecurity (63%) or with Article IV of the BWC that introduces the concept of individual responsibility for upholding and promoting the nonproliferation obligations (64%).

| Question 8. Familiar with the Biological Weapons Convention (BWC) |       | % Respondents (N) |      |  |
|---|-------|-------------------|------|--|
| Yes   |       | 89%               | (42) |  |
| No  |       | 9%                | (4)  |  |
| Don't Know  |       | 2%                | (1)  |  |
|   | Total | 100%              | (47) |  |

| Question 9. Familiar with Provisions for Biosafety and Biosecurity | % Respondents (N) |  |  |
|--|-------------------|--|--|
| Yes  | 63% (26)          |  |  |
| No   | 27% (11)          |  |  |
| Don't Know   | 10% (4)           |  |  |
| Total  | 100% (41)         |  |  |

| Question 10. Aware of Article IV of BWC |       | % Respondents (N) |      |  |
|---|-------|-------------------|------|--|
| Yes                                     |       | 64%               | (30) |  |
| No                                      |       | 28%               | (13) |  |
| Don't Know                              |       | 9%                | (4)  |  |
|   | Total | 100%              | (47) |  |

#### **B.3** 2006 Outreach and Education Training (Questions 11-24)

This section of the survey contains questions regarding participation in and evaluation of the 2006 Outreach and Education Training as well as how the respondents' behavior has been affected by training and education.

**Training participation**. More than one-half of the respondents (57%) participated in the 2006 Outreach and Education Training on the Biological Weapons Convention, Dual-Use in the Life Sciences, and Codes of Conduct.

| Question 11. Participated in 2006 Outreach and Education Training |       | % Respondents (N) |  |  |
|---|-------|-------------------|--|--|
| Yes   |       | 57% (27)          |  |  |
| No  |       | 43% (20)          |  |  |
|   | Total | 100% (47)         |  |  |

**Training effectiveness.** In Questions 13-15, respondents who attended the 2006 Outreach and Education Training were asked to rate the training in terms of conveying information on the BWC, codes of conduct, and dual-use and biosecurity concerns. The scale ranged from 1, indicating "Not effective at all," to 5, indicating "Very effective." More of the respondents rated Training Materials, Venue, and Presentation as effective (4 or 5) versus not effective (1 or 2) and nearly 20% found the Venue and Presentation to be "Very effective."

| Questions 13-15. Effectiveness of 2006 Outreach and Education Training |                      |       |       |       |                   |           |  |
|--|----------------------|-------|-------|-------|-------------------|-----------|--|
|  | Not effective at all |       |       |       | Very<br>Effective |           |  |
|  | 1                    | 2     | 3     | 4     | 5                 | Total     |  |
| 13. Training Materials   | 7% (2)               | 22%(6 | 26%(7 | 37%(1 | 7% (2)            | 100% (27) |  |
| 14. Venue  | 4% (1)               | 11%(3 | 41%(  | 26%(7 | 19% (5)           | 100% (27) |  |
| 15. Presentation   | 7% (2)               | 15%(4 | 30%(8 | 30%(8 | 19% (5)           | 100% (27) |  |

**Preferred type of training**. If a recommended or mandatory training on the BWC and dual-use research were offered, the preferred type of training would be web-based (81%).

| Question 16. Preferred Type of Training |       | % Respondents (N) |      |  |
|---|-------|-------------------|------|--|
| Web-based                               |       | 81%               | (26) |  |
| Classroom Training                      |       | 9%                | (3)  |  |
| Reference Book                          |       | 9%                | (3)  |  |
|   | Total | 100%              | (32) |  |

Changes in research behavior due to bioterrorism concerns. Questions 18 and 19 (Tables 14 and 15) elicit information about whether respondents have made any changes in the past 2 years in how they conduct or manage research because of concerns that knowledge, tools, or techniques from their research might be deliberately misused to facilitate bioterrorism. Most of the respondents (77%) have made no changes. The types of changes that have been made are mainly related to modifications in how information is disseminated (Questions 18-5, 18-7, 18-9) rather than the avoidance of providing information, collaborating, or conducting particular research.

| Question 18. Changes in Research Behavior Due to Bioterrorism Concerns                     | % Yes | (N=47) |
|--|-------|--------|
| 18-1. I decided against conducting a specific research project/experiment                  | 4%    | (2)    |
| 18-2. I decided to shift my research away from an area altogether                          | 4%    | (2)    |
| 18-3. I decided against seeking funding for a proposed research project                    | 2%    | (1)    |
| 18-4. I decided against collaborating with particular scientists, postdocs, students, etc. | 2%    | (1)    |
| 18-5. I limited my conversations about my research   | 17%   | (8)    |
| 18-6. I decided against submitting a manuscript to a journal                               | 2%    | (1)    |
| 18-7. I modified a manuscript  | 9%    | (4)    |
| 18-8. I decided against presenting research at a conference                                | 2%    | (1)    |
| 18-9. I modified a conference presentation   | 11%   | (5)    |
| 18-10. No change ("no" to 18-1 through 18-9)   | 77%   | (36)   |

In Question 19, the 11 respondents who changed their research behavior in the past 2 years due to bioterrorism concerns typed in the sources of the changes.

| Question 19. Sources of Changes in Research Behavior Due to Bioterrorism Concerns     | N |
|---|---|
| Training conducted by PNNL  | 3 |
| Training provided by another laboratory or organization                               | 0 |
| Other related training or education:  | 1 |
| New or emerging guidelines addressing dual-use research                               | 3 |
| Personal reading or research  | 3 |
| Interaction with PNNL personnel familiar with national security issues                | 1 |
| General Security Training and Managing DHS projects                                   | 1 |
| ASM biodefense conference 2007  | 1 |
| ADC   | 1 |
| OPSEC   | 1 |
| Client confidentiality  | 1 |
| Discussion of issues as part of IBC membership  | 1 |
| NSABB request to review guidelines, journal review policies for editors and reviewers | 1 |
| BNL Bio. dept training  | 1 |

**Discussions about dual-use research and codes of conduct**. Questions 22 and 23 refer to discussions about dual-use research and codes of conduct. Most of the respondents (68%) have participated in discussions regarding dual-use research or codes of conduct with management, researcher, or IBC participants. The discussions were largely a result of "New or emerging guidelines addressing dual-use research" and "Personal reading or research," with training also being an inspiration for discussions.

| Question 22. Participated in Discussions Regarding Dual-<br>Use Research or Codes of Conduct | % Respondents (N) |  |
|--|-------------------|--|
| Yes  | 68% (32)          |  |
| No   | 32% (15)          |  |
| Total  | 100% (47)         |  |

| Question 23. Sources of Discussions Regarding Dual-Use Research or Codes of Conduct | % Yes | (N=32) |
|---|-------|--------|
| 23-1. Training conducted by PNNL  | 31%   | (10)   |
| 23-2. Training conducted by another laboratory or organization                      | 0%    | (0)    |
| 23-3. Other related training or organization  | 16%   | (5)    |
| 23-4. New or emerging guidelines addressing dual-use research                       | 66%   | (21)   |
| 23-5. Personal reading or research  | 66%   | (21)   |

**Recommended participants for training.** Respondents were asked to check all groups that they believed should participate in training that covers scientist obligations under the BWC, dual-use risks of research, and codes of conduct. Training is recommended for most groups, with only 6% indicating that there is no need for training of this type.

| Question 24. Recommended Participants for Scientist Obligations Training                    | % Yes (N) |
|---|-----------|
| 24-1. Senior Research Scientists  | 83% (39)  |
| 24-2. Mid-level Research Scientists   | 68% (32)  |
| 24-3. Junior Scientists   | 60% (28)  |
| 24-4. Program/Project Managers  | 79% (37)  |
| 24-5. Laboratory Managers   | 68% (32)  |
| 24-6. IBC/IRB chairs and members  | 76% (35)  |
| 24-7. Research associates/technicians   | 36% (17)  |
| 24-8. Other:  | 13% (7)   |
| Scientists at all levels who actually do or manage potential dual-use research              |           |
| Security Staff, Export Control Staff  |           |
| A graded approach with an awareness level for some and additional info for responsible mgrs |           |
| OS&H and facilities support; others as interested   |           |
| Select Agent officials  |           |
| CDC or Gov't offices funding the research   |           |
| 24-9. There is no need for such training  | 6% (3)    |

## **B.4** Publication and Journal Review (Questions 26-34)

The next section of the survey focuses on experiences with journal manuscripts and on opinions about the roles of journals and professional science societies in the context of the potential of dual-use research.

**Scientific journal experiences**. In Questions 26-29, respondents were asked about their experiences reviewing manuscripts and their awareness of whether journals require reviewers to evaluate manuscripts for knowledge, tools, and techniques with dual-use potential. Most of the respondents have reviewed manuscripts for journals (87%). Of those who have reviewed manuscripts, only 3 (7%) have ever felt that a manuscript they were reviewing contained knowledge, tools, or techniques that could pose a threat to national security, and none of those individuals contacted an editor to raise this concern.

| Question 26. Ever Reviewed Journal Manuscript |       | % Yes (N) |      |
|---|-------|-----------|------|
| Yes   |       | 87%       | (41) |
| No  |       | 13%       | (6)  |
|   | Total | 100%      | (47) |

| Question 27. Reviewed Manuscript Containing Potential Dual-<br>Use Information | % Yes (N) |
|--|-----------|
| Yes  | 7% (3)    |
| No   | 93% (38)  |
| Total  | 100% (41) |

| Question 28. Reviewed Manuscript Containing Potential Dual-<br>Use Information and Contacted Editor |    | % Y  | es  |
|---|----|------|-----|
| Yes   |    | 0%   | (0) |
| No  |    | 100% | (3) |
| Tot   | al | 100% | (3) |

There is variation in respondents' awareness of whether journals require reviewers to evaluate manuscripts for knowledge, tools, and techniques with dual-use potential. Almost one-half of the respondents (43%) did not know if this was the case.

| Question 29. Proportion of Journals Requiring Review for Potential Dual-Use | % Respondents (N) |      |
|---|-------------------|------|
| All of the journals   | 0%                | (0)  |
| Most of the journals  | 11%               | (5)  |
| Some of the journals  | 13%               | (6)  |
| A few of the journals   | 17%               | (8)  |
| None of the journals  | 17%               | (8)  |
| Don't know  | 43%               | (20) |
| Total   | 100%              | (47) |

**Opinions about scientific journal and professional society responsibilities**. A large proportion of respondents agree that "Scientific journals should have guidelines regarding publication of dual-use research" (Question 30) and that "Professional societies should have codes for the responsible conduct of dual-use life sciences research" (Question 32).

| Questi<br>Condu | ions 30-3<br>ict | 2. Scier                | ntific Jou | urnal an               | d Profe | ssional  | Society | Guideli        | nes an   | d Codes   | of   |
|-----------------|------------------|-------------------------|------------|------------------------|---------|----------|---------|----------------|----------|-----------|------|
| 30.             |                  | Scientific<br>Ise resea |            | s should               | d have  | guidelin | es rega | rding pu       | ıblicati | on of dua | al-  |
| Strongly Agree  |                  | e Agree                 |            | Neut<br>No Op          |         | Disag    | gree    | Stroi<br>Disag | 0,       | Tot       | al   |
| 23%             | (11)             | 60%                     | (28)       | 9%                     | (4)     | 6%       | (3)     | 2%             | (1)      | 100%      | (47) |
| [no 31          | in web su        | ırvey]                  |            |                        |         |          |         |                |          |           |      |
| 32.             |                  | Profession              |            |                        |         |          |         | des for t      | he resp  | onsible   |      |
| Strongly Agree  |                  | Agree                   |            | Neutral/<br>No Opinion |         | Disag    | gree    | Stron<br>Disag | 0,       | Tot       | al   |
| 32%             | (15)             | 51%                     | (24)       | 11%                    | (5)     | 4%       | (2)     | 2%             | (1)      | 100%      | (47) |

**Professional society membership.** Few respondents are members of professional societies that have codes of responsible conduct for dual-use research (18%) and nearly one-half did not know whether the societies in which they are members have this type of conduct codes.

| Question 34. Member of Professional Science Societies with Codes of Conduct | % Responde | nts (N) |
|---|------------|---------|
| Yes   | 18%        | (8)     |
| No  | 38%        | (17)    |
| Don't Know  | 44%        | (20)    |
| Total   | 100%       | (45)    |

### **B.5** Minimizing Potential Threat to National Security (Questions 38-61)

In Questions 38-61 of the survey, respondents were asked to evaluate "possible actions that could be taken to minimize the potential threat to national security that may be posed by knowledge, tools, or techniques from dual-use research." Opinions were requested regarding several areas—Roles and Responsibilities of Scientists, Access to Agents and Equipment, Research Findings, Training, and Review and Funding.

Role and responsibilities of scientists. Respondents generally believe that it is the responsibility of the scientists to evaluate dual-use potential of their research and to assure their institution of this assessment (Questions 38-39). Requiring scientists to take an oath (Question 40) or obtain certification (Question 41) were considered to be less likely to minimize the potential threat to national security, but there was some support for these options. There was also some disagreement about whether greater Federal oversight would reduce risk (Question 42)—60% disagreed, but more than one-quarter of the respondents thought that it would reduce risk.

| Questi   | Questions 38-42. Role and Responsibilities of Scientists   |                   |                   |                        |                   |           |                      |                |        |                             |        |
|----------|--|-------------------|-------------------|------------------------|-------------------|-----------|----------------------|----------------|--------|-----------------------------|--------|
| 38.      |  |                   |                   |                        |                   | lucting a |                      | l evalua       | tion o | f the dua                   | ıl-use |
| Strongly | Agree  | Agr               | ee                | Neu<br>No Op           |                   | Disa      | gree                 | Stron<br>Disag |        | To                          | tal    |
| 19%      | (9)  | 60%               | (28)              | 11%                    | (5)               | 11%       | (5)                  | 0%             | (0)    | 100%                        | (47)   |
| 39.      | 39. Scientists providing formal assurance to their institution that they are assessing their work for dual-use potential (e.g. such as following dual-use recommendations or guidelines) |                   |                   |                        |                   |           |                      |                |        |                             |        |
| Strongly | Agree  | Agr               | ee                | Neu<br>No Op           | ,                 | Disa      | gree                 | Stron<br>Disag |        | To                          | tal    |
| 6%       | (3)  | 53%               | (25)              | 19%                    | (9)               | 21%       | (10)                 | 0%             | (0)    | 100%                        | (47)   |
| 40.      |  | similar<br>respon | to med<br>sibly a | dicine's<br>nd guar    | Hippod<br>d agair | cratic Oa | ath, to o<br>erate m | carry out      | resea  | take an<br>arch<br>knowledo |        |
| Strongly | Agree  | Agree             |                   | Neutral/<br>No Opinion |                   | Disa      | gree                 | Stron<br>Disag |        | To                          | tal    |
| 0%       | (0)  | 19%               | (9)               | 30%                    | (14)              | 32%       | (15)                 | 19%            | (9)    | 100%                        | (47)   |

| Questions 38-42. Role and Responsibilities of Scientists                      |     |        |          |               |         |         |          |                |       |      |      |
|---|-----|--------|----------|---------------|---------|---------|----------|----------------|-------|------|------|
| 41. Requiring certification for researchers conducting some dual-use research |     |        |          |               |         |         |          |                |       |      |      |
| Strongly Agree  |     | Agree  |          | Neut<br>No Op |         | Disa    | gree     | Stror<br>Disaç | 0,    | Tot  | al   |
| 6%  | (3) | 28%    | (13)     | 15%           | (7)     | 34%     | (16)     | 17%            | (8)   | 100% | (47) |
| 42.   |     | Provid | ing grea | ater fede     | eral ov | ersight | of dual- | use res        | earch |      |      |
| Strongly Agree  |     | Agı    | ee       | Neut<br>No Op |         | Disa    | gree     | Stror<br>Disaç |       | Tot  | al   |
| 0%  | (0) | 28%    | (13)     | 11%           | (5)     | 43%     | (20)     | 17%            | (8)   | 100% | (46) |

Access to agents and equipment. There is little agreement in the opinions about whether placing greater restrictions on access to specific biological agents or toxins would minimize the potential threat to national security (Question 45). About one-half of the respondents agree, while the other half disagrees. A majority of respondents (66%) believes that requiring licensure of certain biological equipment would not minimize potential threat.

| Questi         | ons 45 | -46. Ro        | le and  | Respons              | sibilitie     | s of Sc | ientists |               |          |          |       |
|----------------|--------|----------------|---------|----------------------|---------------|---------|----------|---------------|----------|----------|-------|
| 45.            |        | Placing toxins | ggreate | er restric           | tions         | on acce | ss to s  | pecific k     | oiologi  | cal agen | ts or |
| Strongly       | Agree  | Agı            |         |                      | ral/<br>inion | Disa    | gree     | Stroi<br>Disa | 0,       | Tot      | al    |
| 11%            | (5)    | 34%            | (16)    | 13%                  | (6)           | 32%     | (15)     | 11%           | (5)      | 100%     | (47)  |
| 46.            |        |                |         | nsure of<br>ience re |               |         | gical ed | quipmen       | t that i | s comm   | only  |
| Strongly Agree |        | Agı            | ·ee     | Neut<br>No Op        |               | Disa    | gree     | Stroi<br>Disa | 0,       | Tot      | al    |
| 2%             | (1)    | 19%            | (9)     | 13%                  | (6)           | 38%     | (18)     | 28%           | (13)     | 100%     | (47)  |

**Research findings**. Questions 49-52 ask respondents whether actions related to research findings would minimize potential threat to national security. Responses are varied in this area, with about 20% of respondents having neutral or no opinions on these actions, and the rest of the responses relatively split between "disagree" and "agree." There appears to be no pattern across groups, except that a larger percentage of respondents who took the 2006 Outreach and Education Training agreed with Question 49 (12 out of 26, or 45%) versus those who did not take the training (5 out of 20, or 25%).

| Questi  | Questions 49-52. Research Findings   |                  |      |                        |        |                 |          |                |                      |          |        |
|---|--|------------------|------|------------------------|--------|-----------------|----------|----------------|----------------------|----------|--------|
| 49.   |  |                  |      |                        |        | losure<br>commu |          | ils abou<br>n  | t the r              | esearch  | or its |
| Stron<br>Agre   |  | Agr              | ee   | Neutral/<br>No Opinion |        | Disa            | Disagree |                | Strongly<br>Disagree |          | tal    |
| 0%  | (0)  | 37%              | (17) | 24%                    | (11)   | 24%             | (11)     | 15%            | (7)                  | 100%     | (46)   |
| 50.   | 50. Altering or removing certain experimental methods or findings prior to publication or presentation |                  |      |                        |        |                 |          |                |                      |          |        |
| Strongly<br>Agree                                       |  | Agr              | ee   | Neur<br>No Op          |        | Disa            | gree     | Stron<br>Disag | 0,                   | То       | tal    |
| 2%  | (1)  | 43%              | (20) | 15%                    | (7)    | 22%             | (10)     | 17%            | (8)                  | 100%     | (46)   |
| 51.   |  | Placin<br>potent |      | ictions                | on pub | lication        | of find  | lings ba       | sed or               | า dual-น | se     |
| Stron<br>Agre   |  | Agr              | ee   | Neur<br>No Op          | ,      | Disa            | gree     | Stron<br>Disag | 0,                   | То       | tal    |
| 0%  | (0)  | 36%              | (17) | 23%                    | (11)   | 28%             | (13)     | 13%            | (6)                  | 100%     | (47)   |
| 52. Classifying research findings on dual-use potential |  |                  |      |                        |        |                 |          |                |                      |          |        |
|   | Strongly<br>Agree  |                  | ee   | Neur<br>No Op          | ,      | Disa            | gree     | Stron<br>Disag | 0,                   | То       | tal    |
| 4%  | (2)  | 42%              | (19) | 22%                    | (10)   | 13%             | (6)      | 18%            | (8)                  | 100%     | (45)   |

**Training**. The majority agrees that training about dual-use research, policies, and practices would minimize the potential threat to national security, especially training laboratory staff, students, and visiting scientists (Questions 55-56). At least one-half of the respondents believe that threat to national security would be minimized if institutions provided mandatory training for scientists, while nearly 25% had neutral or no opinion regarding this action and 26% disagreed.

| 55.           |     | visitin<br>practio                                   | g scien   | itists ab<br>ninimiz                                    | out du  | al-use r  | esearcl                                 | n includ                | ling po                          | tudents<br>olicies a<br>nation fr  | nd                                 |
|---------------|-----|--|---|---|---|---|---|-------------------------|----------------------------------|------------------------------------|------------------------------------|
| Stron<br>Agre | 0,  | Agr  | ee  | Neut<br>No Op   | ,   | Disag   | ree                                     | Strongly<br>Disagree To |                                  |                                    | tal                                |
| 11%           | (5) | 65%  | (30)  | 7%  | (3)   | 15%   | (7)                                     | 2%                      | (1)                              | 100%                               | (46)                               |
| 56.           |     |  | sity an   |   |   |   |   |                         |                                  |                                    |                                    |
|               |     | materi<br>that kr                                    | als on oned   | dual-us<br>ge, tool<br>to natio                         | e life s<br>s and t<br>onal se  | ciences<br>echniqu                                | resear                                  | ch incluuch res         | uding s<br>earch                 | the pote                           | ntial                              |
| Stron<br>Agre |     | materi<br>that kr                                    | als on on one of the contract | dual-us<br>ge, tool                                     | e life s<br>s and t<br>onal se<br>ral/                                      | ciences<br>echniqu                                | resear<br>ies of s                      | ch inclu                | iding search                     | the pote                           | ntial<br>uld                       |
| Stron         |     | materi<br>that kr<br>pose a                          | als on on one of the contract | dual-us<br>ge, tool<br>to nation                        | e life s<br>s and t<br>onal se<br>ral/<br>inion                             | ciences<br>echniqu<br>curity.                     | researdies of s                         | ch incluuch res         | iding search                     | the pote<br>that co                | ntial<br>uld                       |
| Stron<br>Agre | ee  | materi<br>that kr<br>pose a<br>Agr<br>63%<br>Institu | als on consider threat (29)   | dual-us<br>ge, tool<br>to natio<br>Neut<br>No Op        | e life s<br>s and t<br>onal se<br>ral/<br>inion<br>(6)                      | ciences<br>echniquecurity.  Disage 13%  datory tr | researd<br>les of solutions             | Stron<br>Disag          | ading search gly ree (0)         | the pote<br>that co                | ential<br>uld<br>tal<br>(46)       |
| Stron<br>Agre | (5) | materi<br>that kr<br>pose a<br>Agr<br>63%<br>Institu | als on nowledge threat (29) tions pose life s   | dual-us<br>ge, tool<br>to natio<br>Neut<br>No Op<br>13% | e life s<br>s and t<br>onal se<br>ral/<br>inion<br>(6)<br>g mand<br>s reser | ciences<br>echniquecurity.  Disage 13%  datory tr | researdes of solutions of solutions (6) | Stron<br>Disag          | dding search gly ree (0) entists | the pote<br>that cou<br>To<br>100% | ential<br>uld<br>tal<br>(46)<br>ng |

**Review and funding.** Requiring review of proposals for dual-use potential prior to submission received mixed results—47% agreed that this would help minimize potential threat to national security and 43% disagreed. While the majority of respondents (62%) agreed that requiring grantees to attest that dual-use implications were considered when applying for grants would help minimize potential threat, more than 25% disagreed.

| Questio           | ons 60 | )-61. Re | eview a  | nd Fund                           | ling   |           |         |                |         |          |      |
|-------------------|--------|----------|----------|-----------------------------------|--------|-----------|---------|----------------|---------|----------|------|
| 60.               |        | use po   | otential | l grant p<br>by an a<br>er's inst | ppropi | riate inc | dividua | l or boa       | rd (suc | ch as an |      |
| Strongly<br>Agree |        | Agree N  |          | Neuti<br>No Opi                   |        | Disa      | gree    | Stron<br>Disag |         | То       | tal  |
| 9%                | (4)    | 38%      | (18)     | 11%                               | (5)    | 30%       | (14)    | 13%            | (6)     | 100%     | (47) |
| 61.               |        |          | ney hav  | ncies red<br>e consid             |        |           |         |                |         |          |      |
| Strongly<br>Agree |        | Agr      | ee       | Neuti<br>No Opi                   |        | Disa      | gree    | Stron<br>Disag |         | То       | tal  |
| 15% (7) 47% (22)  |        | (22)     | 11%      | (5)                               | 21%    | (10)      | 6%      | (3)            | 100%    | (47)     |      |

**Opinions about bioterrorism and dual-use research**. More respondents disagreed than agreed that "Funding agencies would be less likely to fund grant proposals if the proposed research had dual-use potential." However, almost one-third of respondents were neutral or had no opinion and more than one-quarter of respondents at least agreed with the statement.

|                                      | Question 64. Funding agencies would be less likely to fund grant proposals if the proposed research had dual-use potential |  |     |     |               |    |      |      |                |  |    |     |
|--------------------------------------|--|--|-----|-----|---------------|----|------|------|----------------|--|----|-----|
|                                      | Strong<br>Agre   |  | Agı | ree | Neut<br>No Op |    | Disa | gree | Stron<br>Disag |  | To | tal |
| 2% (1) 24% (11) 30% (14) 39% (18) 49 |  |  |     |     |               | 4% | (2)  | 100% | (46)           |  |    |     |

In Questions 66 and 67, respondents indicated the percent chance that an act of bioterrorism would occur somewhere in the next 5 years. Respondents believe the risk is greater "in the world" than "in the United States."

| Questions 66-67. Percent Chance of Bioterrorism |      |        |         |  |  |  |  |
|---|------|--------|---------|--|--|--|--|
|   | Mean | Median | Range   |  |  |  |  |
| 66. In the world                                | 57%  | 50%    | 2%-100% |  |  |  |  |
| 67. In the United States                        | 37%  | 25%    | 1%-100% |  |  |  |  |

One-half of the respondents believe that there is at least a 25% chance "that knowledge, tools or techniques from *dual-use life sciences* research will facilitate an act of bioterrorism somewhere in the world in the next five years."

| Question 68. Percent Chance Bioterrorism Facilitated by Dual-Use Research                               |      |        |         |  |  |  |  |  |  |
|---|------|--------|---------|--|--|--|--|--|--|
|   | Mean | Median | Range   |  |  |  |  |  |  |
| 68. Percent chance that knowledge, tools or techniques from <i>dual-use life</i>                        |      |        |         |  |  |  |  |  |  |
| sciences research will facilitate an act of bioterrorism somewhere in the world in the next five years. | 31%  | 25%    | 0%-100% |  |  |  |  |  |  |

The results to Questions 70-73 indicate that the means of communication that have a greater ability to provide sufficient information for an individual with college-level life science training to deliberately create a harmful biological agent are scientific journal articles and internet.

| Questions 70-73. Means of Communication Sufficient Sources for Creation of Harmful Biological Agent |          |          |            |           |  |  |
|---|----------|----------|------------|-----------|--|--|
|   | Yes      | No       | Don't Know | Total     |  |  |
| 70. Scientific journal articles   | 64% (30) | 19% (9)  | 17% (8)    | 100% (47) |  |  |
| 71. Presentations at scientific conferences or meetings   | 40% (19) | 49% (23) | 11% (5)    | 100% (47) |  |  |
| 72. Personal communications (e.g., e-mail, phone calls)   | 49% (23) | 26% (12) | 26% (12)   | 100% (47) |  |  |
| 73. Internet  | 77% (36) | 11% (5)  | 13% (6)    | 100% (47) |  |  |

#### **B.6** Respondent Background

Most of the respondents (68%) have doctorate degrees or the equivalent.

| Question 76. Highest Educational Degree Awarded               | % Responde | nts (N) |
|---|------------|---------|
| Bachelor's degree or equivalent (e.g., BS, BA, AB)            | 4%         | (2)     |
| Master's degree or equivalent (e.g., MS, MA, MBA, etc.)       | 17%        | (8)     |
| Doctorate or equivalent (e.g., PhD, DSc, EdD, etc.)           | 68%        | (32)    |
| Other professional degree (e.g., JD, LLB, MD, DDS, DVM, etc.) | 6%         | (3)     |
| Joint doctorate and professional degree (e.g. Ph.D. and MD)   | 4%         | (2)     |
| Other   | 0%         | (0)     |
| Total   | 100%       | (47)    |

The year that the highest degree was awarded ranged from 1969 to 2007.

| Question 77. Year Highest Educational Degree Awarded          |      |        |           |  |
|---|------|--------|-----------|--|
|   | Mean | Median | Range     |  |
| 77. In what year was your highest educational degree awarded? | 1987 | 1985   | 1969-2007 |  |

Primary areas of work or study vary across respondents. Respondents represented the areas listed below.

| Question 78. Primary Scientific Discipline |
|--|
| Biochemistry                               |
| Biodefense                                 |
| Bioinformatics                             |
| Biological Safety/Security                 |
| Biomedical Engineering                     |
| Biotechnology                              |
| Cell Biology                               |
| Chemistry                                  |
| Geology/Soil Sciences/Geography            |
| Health Physics                             |
| Immunology                                 |
| Life Sciences                              |
| Medicine                                   |
| Microbiology                               |
| Molecular Biology                          |
| Nanotechnology                             |
| Oceanography                               |
| Physics                                    |
| Risk Analysis                              |

The respondents' roles are varied, with the largest group being Senior Research Scientists (43%).

| Question 80. Current Role % Responder   |       | nts (N) |      |
|---|-------|---------|------|
| Senior Research Scientist   |       | 43%     | (18) |
| Mid-level Research Scientist  |       | 17%     | (7)  |
| Junior Scientist  |       | 0%      | (0)  |
| Program/Project Manager   |       | 19%     | (8)  |
| Laboratory Manager  |       | 10%     | (4)  |
| Research associate/technician   |       | 0%      | (0)  |
| Other (including Biological Safety Officer, Research Ops Manager, PostDoc, and Institutional Board Members) |       | 12%     | (5)  |
|   | Γotal | 100%    | (42) |

# Appendix B Qualitative Analysis Report

# **Education and Outreach in the Life Sciences**

## **Qualitative Analysis Report**

October 2008

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#### 1. Introduction

Rapid developments in biotechnology and the life sciences bring significant benefits, but also create new security challenges. In recent years, members of the scientific and security policy communities have raised concerns about the potential for misuse of knowledge, tools, and techniques for purposes of bioterrorism. Such research is sometimes called "dual-use" research because, although the research is intended for beneficial purposes only, it could be misapplied. The role of scientists, institutions, scientific societies, and the government is critical in fostering an environment that enhances both the scientific enterprise and national security.

In 2004, the U.S. government established the National Science Advisory Board on Biosecurity (NSABB) under the auspices of the National Institutes of Health (NIH) to contemplate the possibility and impact of greater oversight for life sciences research to prevent or mitigate deliberate misuse. Similarly, the U.S. Department of Energy (DOE) is considering how to respond to emerging issues of concern related to dual-use. Other federal agencies are planning to issue further guidelines and considering additional policies regarding responsible scientific research. Discussion sessions on this topic were also conducted by Pacific Northwest National Laboratory (PNNL) for the DOE's Office of International Regimes and Agreements (NA-243) at ten of the national laboratories in Fall 2006.

The DOE's National Nuclear Security Agency (NNSA) asked PNNL to consider the role of individual scientists in upholding safety and security. The views of scientists were identified as being a critical component of this policy process. Therefore, scientists, managers, and representatives of Institutional Biosafety Committees (IBCs) at the national labs were invited to participate in a brief survey that was designed to:

- Evaluate the function of the 2006 outreach and education seminars that were conducted by the U.S. DOE;
- Assess the opinions of scientists about potential future mechanisms to address dual-use concerns in the life sciences community;
- Gather data on scientists' attitudes toward potential security risks from agricultural, public health, and biomedical research;
- Give scientists a voice in the policy-making process.

In addition, three focus groups were conducted with scientists, managers, and IBC representatives to discuss some of the questions related to education, outreach, and codes of conduct in further detail and gather additional input on biosecurity and dual-use awareness at the laboratories. The overall purpose of this process was to identify concerns related to these topics and to gather suggestions for creating an environment where both the scientific enterprise and national security are enhanced.

The information gathered through the survey and focus groups will be instrumental in informing the U.S. position at the Biological Weapons Convention (BWC) Experts' Group meeting in August 2008, as well as to move toward a sustainable mechanism for biosecurity education and awareness. It will also guide DOE action in developing educational tools that will help promote a laboratory culture of responsibility.

#### 2. Methods

The PNNL Project Director sent an e-mail invitation to individuals who participated in the 2006 training and other points of contact at each of the national laboratories (N=202). Of these, 173 were delivered and 29 were returned undeliverable. This e-mail introduced the purpose of the focus groups and invited individuals to participate. Separate times were established for managers, scientists, and IBC representatives. Each of these groups was offered a choice of times, and the date and time that was convenient for the majority of individual participants was selected for each of the three groups.

Additional follow-up e-mails were sent to points of contact at each of the laboratories to encourage participation. The following table summarizes the final focus group participation.

| Focus Group Type    | Date          | # of<br>Participants | Labs Represented                           |
|---------------------|---------------|----------------------|--|
| Scientists          | June 11, 2008 | 5                    | Brookhaven, Los Alamos, Oak<br>Ridge, PNNL |
| Managers            | June 12, 2008 | 5                    | Idaho, Los Alamos, NREL, PNNL              |
| IBC representatives | June 18, 2008 | 5                    | Berkeley, Los Alamos, Oak Ridge,<br>Sandia |

In addition, comments provided by three individuals who were not available to attend the IBC focus group were integrated into the analysis.

#### 3. Results

Results of the focus groups are presented below. We begin by describing the apparent level of awareness of dual-use risk and the perceived need for increased awareness and/or training. Next, we describe concerns raised by participants regarding current developments related to dual-use guidelines, education and awareness training, and codes of conduct. Finally, we present participants' perceptions of the usefulness of training materials as well as recommendations for the format and delivery of these materials. A copy of the focus group moderator's guide used to conduct these groups is found in Appendix B1.

#### 3.1 Awareness of Dual-Use Risk

Focus group participants were asked about their awareness of dual-use risk and the risk they perceived in the work they conducted themselves or in their own workgroup (Section 3.1.1). Respondents were also asked for their opinions as to what constitutes being a "responsible scientist" when dual-use is a possibility (Section 3.1.2). Finally, they were asked for their perspectives on groups (Section 3.1.3) or scientific disciplines (Section 3.1.4) that may require a heightened level of awareness.

#### 3.1.1 Current Level of Awareness

The current level of awareness varies among individuals in different areas of the life sciences. Individuals perceived to have the greatest awareness of the issues were generally seen as those who worked with Select Agents or pathogens and also those with higher levels of security clearance. In addition, those working for national security clients such as the Department of Homeland Security were also seen as having higher levels of awareness. The reasons for that higher awareness were related to

both considerations of higher risk for dual-use associated with that type of research, as well as increased regulations and procedures in place for individuals conducting projects in those areas. This was a common perception across all three groups.

Other scientists working in the life sciences in the national laboratories – for example, those working with organisms at BSL-2 level or below, those who worked on NIH-funded projects, and those who conducted more "fundamental" or basic science research – were seen as generally aware of the potential for dual-use or misuse of research, but were not driven by this consideration in conducting their own work. As one manager noted, "If you had somebody that's really focused on understanding an environmental organism that's related to bioremediation, their head is in that space. It's not necessarily focused on how somebody could use the research they're doing and applying it to a biothreat agent." It was also stated that "scientists may be intellectually aware of dual-use issues, but they do not necessarily connect these issues to their research on a day-to-day basis." Reasons for this lower level of awareness were generally seen as due to the lower level of potential for dual-use inherent in the research and the belief that you cannot guard against all possible risk. General awareness was driven by cases where research methods and/or results were published in scientific or popular media rather than by examples from scientists' own work. Scientists in particular believed that while "there is always the potential for misuse," there are safety measures in place to mitigate these risks. Most scientists do not see security as a central focus of their work.

Scientists also made this distinction about the risks inherent in their own work. Those working below BSL-2 tended to see their own research as having "minimal" risk related to dual-use. A few mentioned the potential for misuse, but did not feel that it could be a widespread use. Those working with Select Agents or pathogens felt that risks may exist, but these were mitigated by following safety practices, legal guidelines, and client requirements regarding information sharing. Scientists in this category required permits to obtain certain organisms, had institutional- and client-level review procedures for dual-use considerations, and (depending on the client), limited distribution and publication of some research.

Across focus groups, the lowest general level of awareness was considered to be in individuals working in the academic sector, while scientists working in the national laboratories were considered to have a generally high level of awareness. University researchers were seen as having fewer regulations placed on the types of work they could conduct. Participants across the focus groups also noted that publications are a significant driver of academic research, and that academic researchers would resist dual-use reviews or other activities that could be a potential hindrance to publication.

#### 3.1.2 Being a "Responsible Scientist" When Dual-Use Considerations Exist

Focus group participants believed that there was a "shared responsibility system" in the national laboratories. A number of individuals and organizations reviews are responsible for safety and security, including the Principal Investigator (PI) who reviews the research direction, project managers and line managers that approve of proposals, the Institutional Biosafety Committee (and biosafety officer), Institutional Review Boards (IRBs) that consider legal and regulatory requirements, and the authorized derivative classifier (ADC). When considering classification prior to release of research methods or findings, the ADC has a responsibility to consider dual-use. These and other institutional controls help ensure that inappropriate material is not released or inappropriate research planned.

In project planning, managers believed it was the role of the PI to understand the potential for dual-use in the project and modify experiments to mitigate the potential risk. However, it was noted that the PI should also have the project reviewed by the IBC to assess potential dual-use risk, and obtain approval to proceed with the research, rather than making an independent determination. Additionally, the Scientist group thought that PIs have a responsibility to use common sense and not disclose inappropriate information, even to other scientists during discussions or at scientific conferences.

Scientists in particular believed that their institution had a responsibility to set up clear policies and procedures to assist them in understanding where the line was in pursuing research with dual-use potential. Most believed that their institutions had adequate protections in place and that the majority of researchers were responsible and would not release inappropriate materials. However, managers warned about over-reliance by PIs and others in the laboratory on the organizational systems, reviews, and protections that are in place. It was considered that there was potential for high variability in assessing dual-use risk, and that reviewers may need reminders to conduct their reviews based on dual-use considerations. This perspective is given credence by the view of one IBC member, who noted that other than for Select Agent work, "I don't even think that we consider dual-use even in IBC meetings, unless it's really so obvious. Everybody understands that in any laboratory, in any facility, any protocol can be misused or abused if the intention is there. That's a given in life sciences..." A significant challenge is that there is no clear line that delineates research of concern. Some research clearly has high-risk; some clearly has low risk. However, the majority of research falls somewhere in the middle – where that research has clear benefit, but could be misused by an individual with malicious intent – and so it is difficult to identify the risk posed from that research.

Managers noted that gaps that may stem from variability in individual judgment are mitigated by defense-in-depth -- having redundant systems for review by individuals and committees.

A further example of defense-in-depth is in safeguards, based on editorial board policies for reviewers and submitters to consider dual-use considerations, that have been built into the publication system. However, participants admit that these procedures are sometimes inadequate and allow for some publications that one IBC member "wondered how they got through the review gauntlet without somebody raising a red flag."

A significant minority of individuals in each group believed that there should not be excessive restrictions on sharing information and publications due to dual-use considerations except for the most extreme examples. Several related reasons for this view were put forth:

- Research is happening on an international basis outside of the national security system and cannot be stopped.
- Much of the potential dual-use research also has beneficial aims.
- It is better to use technological solutions to keep ahead of the risk rather than assuming that the release of information can be prevented.
- A nuclear model for nonproliferation is inadequate to the life sciences because there are so many "gray areas" where there is a potential for misuse, but also the potential for great advances.
- Restricting publication just leads to the duplication of effort by other credible laboratories and a waste of resources.

#### 3.1.3 Perspectives on Who Should Be Aware

Managers and scientists relied on the IBC and ADCs to be aware of dual-use issues and thought that individual with these responsibilities needed to be explicitly aware of dual-use concerns. All the groups thought it would be valuable to provide some formal training on dual-use research of concern to IBC members. IBC participants also thought that additional awareness for IBC members would be valuable to ensure that all members (especially new members) were fully cognizant of dual-use when reviewing projects. IBCs were further seen as having an important role to play in ensuring wide-spread education of scientists in the lab. IBC participants thought it would be helpful for project managers to be aware of these issues since they give final approval for proposals. Other audiences mentioned as needing additional awareness and education included: the public, students, foreign nationals, and technicians.

None of the groups saw a particular need to provide explicit training to junior scientists versus senior scientists on these issues. All groups saw that some senior scientists in their institutions were not aware of these issues and could use additional awareness, while some more junior scientists working on higher risk research might be aware already. However, as a caveat, several managers did think that additional experience could help junior scientists in determining what constituted a dual-use concern and what did not. In addition, some managers saw a need for increased awareness for scientists working on NIH-funded research versus those with national security clients who already have greater awareness.

#### 3.1.4 Perspectives on Which Areas/Disciplines Should Be Aware

In terms of risk relating specifically to one scientific discipline or another, participants saw that life science work was becoming increasingly interdisciplinary. While experimental biologists may already have some level of awareness of these issues; additional awareness of dual-use concerns may be needed by, *inter alia*, mathematical modelers, physical modelers, material scientists, and those working in nanotechnology. As noted earlier, participants believed that awareness was critical for those who work in the area of Select Agents and biodefense countermeasures and detection – however a high level of awareness may already exist for these groups.

#### 3.2 Need for Increased Awareness and/or Training

Participants were asked about factors that have influenced current levels of awareness in their laboratories, including changes in the level of awareness over time (Section 3.2.1), as well as their perceptions about additional training needs (Section 3.2.2).

#### 3.2.1 Factors that Influence Current Levels of Awareness

Most groups were fairly evenly split between those who saw that awareness had increased in their laboratory in the last few years versus those who thought that awareness had not changed much recently. Factors accounting for increased awareness noted across the three groups are noted in Table 1. Drivers for increased awareness and discussion include: the training held by PNNL, issues in the news, (increased but now waning interest after 9/11 and the anthrax attacks), client-driven requirements for proposals or project review, and review of projects by IBCs.

As noted earlier, however, the level of awareness shown by different individuals depends on the types of research they conduct. Factors that contributed to lower levels of awareness included: working on research perceived as less risky, lack of consensus around what constitutes a dual-use concern, lack of

technical expertise to be able to identify a dual-use issue, and lack of interest (particularly among academic researchers) who do not want publication restrictions. IBC members commented that one should not expect the same level of awareness between researchers working with Select Agents and researchers working with cancer, for example. Scientists also noted that, while increased IBC oversight occasions some restrictions on the types of work they can do, it generally only involves changes in the paperwork and planning requirements rather than the nature of the research itself.

Table 1. Factors that influence changes in awareness across focus groups

|  | Managers | IBC | Scientist |
|--|----------|-----|-----------|
| PNNL training/brown bag held in 2006                   | <b>✓</b> | ✓   | ✓         |
| Issues in the popular media or publications of concern | ✓        | ✓   |           |
| Increased awareness after 9/11 and anthrax attack      |          | ✓   |           |
| Discussion around proposals with such requirements     |          | ✓   | ✓         |
| Awareness due to client directive and regulations      |          | ✓   | ✓         |
| Local incident of anthrax found at the laboratory      |          | ✓   |           |
| Awareness after creation of IBC                        |          |     | ✓         |
| Awareness due to teaching of classes on related topics |          |     | ✓         |

#### 3.2.2 Perceived Need for Additional Awareness and/or Training to Inform Scientists of Risks

Focus group participants were mixed in their perceptions of the need for additional awareness and/or training for scientists in the life sciences. IBC members and managers generally saw a value in additional awareness for most scientists. However, they saw this as generally working best through a tiered system that would offer introductory information to scientists working in less risky areas, and more extensive training for those conducting more risky research, such as with Select Agents. Those working with Select Agents may already have a level of basis awareness, so training should focus on specific topics or areas of interest, such as the Biological Weapons Convention, as well as on applied examples and case studies.

Scientists, on the other hand, were more mixed in their views about the need for further training or higher levels of awareness. Some thought that heightened awareness could be valuable for those who do not consider dual-use on a daily basis. However, others believe that sufficient information and protections are available to those who need them in the form of existing safety guidelines, and that additional awareness or formal training is not needed.

Focus group participants observed that additional training may be valuable for the following groups:

- Institutional Biosafety Committees. IBCs could benefit from additional training to ensure that members (both old and new) are taking dual-use issues into consideration when conducting reviews. IBCs should also be made aware of changing regulations and guidelines in this field, such as codes of conduct and NSABB guidelines for dual-use research of concern.
- *Trainees and interns*. These types of individuals are given training in proper laboratory procedures but are rarely provided with a broader rationale behind the work they are conducting. Giving them additional information about dual-use concerns may be a helpful building block as they complete their degrees and move into careers in science.

- Security officers. Security officers could play a greater role in preventing inappropriate release of information. However, most are trained in physical sciences and do not have the background to fully understand dual-use concerns in the life sciences.
- Authorized Derivative Classifiers. As with IBCs, ADCs can serve as a valuable safety net to ensure that inappropriate content is not published. ADCs primarily review work for classification issues, so may need additional training on *dual-use*; however, many will be knowledgeable about these issues.
- Foreign nationals. There are restrictions on the type of information and training that can be provided to foreign nationals (as opposed to U.S. citizens) in the national laboratories. In a security clearance environment, this puts restrictions on the amount of information that can be provided about *dual-use* without revealing classified information.
- *Project managers and higher level managers*. These individuals have the responsibility for approving new proposals. It would be valuable for them to consider dual-use concerns as they review proposals.
- *Universities*. Universities may need education and training about the *dual-use* risks of research. Academic researchers have a responsibility for training future researchers, yet they are in general less aware of dual-use issues than are researchers in the national laboratories. Introducing students to these concepts while still in school can reduce their learning curve as new researchers.

#### 3.3 Concerns in Scientific Community Regarding Current Developments

Focus group participants expressed concerns about some of the current developments related to dual-use and biosecurity concerns. The National Science Advisory Board for Biosecurity (NSABB), a Federal advisory panel for NIH, is developing a sample code of conduct related to these types of issues. The document is fairly generally focused, and intended to be put forward as a sample code that organizations can adopt if desired, focus group participants had some reservations about putting forward such a document as well as future implications of the development of such a standard. This code is still in draft form.

A common theme across focus groups was that a *mandated* code of conduct or set of guidelines related to *dual-use* would be negative. Depending on how such a code would be implemented, it would tend to impose unneeded and inappropriate regulations on many projects that do not warrant it and would tend to constrain science unnecessarily. As an IBC member noted, "I think we are all concerned about stifling good science by mandating something that becomes too restrictive."

Focus group participants had varying reactions to *voluntary* guidelines or codes of conduct. Some participants across groups believed that additional guidance and consensus about what constitutes *dualuse* would be valuable as a clarification for researchers. If such guidance were included in requests for proposals, it would enable researchers to understand the review criteria by which dual-use concerns would be judged. Additional guidance would encourage greater consistency in identifying the types of research that constitute a dual-use concern versus those where *dual-use* is not of great concern. Voluntary adherence to guidelines could be viewed as a competitive advantage for national laboratories versus university researchers if they were seen as adhering to a higher standard of conduct for certain types of research. Guidelines could also tend to engender a culture of responsibility.

While the all groups saw general benefit in voluntary guidelines, there was an almost universal concern that even voluntary standards could become a slippery slope that would lead to more restrictions in the form of additional policies, procedures, or training that would not be needed by all groups equally. Some theorized that such guidance could also eventually lead to increased regulations such as by the Department of Defense or NNSA and thus become a mandate. As one manager noted, "*The devil is in the details of implementation*." Scientists also were concerned about whether it would be possible to develop one set of standards that could adequately address all situations. A minority of scientists believed a code of conduct was not needed at all for the life sciences and for the national laboratories. These scientists saw a more critical need for this in other science fields, such as chemistry, where the potential for misuse of research was perceived as greater or in other settings, such as universities.

#### 3.4 Training Materials

Focus group participants were specifically asked for their opinions related to the development of training materials (Section 3.4.1), the format and content of such materials (Section 3.4.2), organizations that would be credible to develop such material (Section 3.4.3), and whether such materials would be used if they were made available (Section 3.4.4).

#### 3.4.1 Usefulness of Training Materials Focusing on BWC, Dual-Use, and Scientific Ethics

As noted in Section 3.2.2, focus group participants found that additional training and materials related to the Biological Weapons Convention, dual-use, and scientific ethics could be useful for various groups in the laboratory. Across focus groups, participants agreed that the PNNL training conducted in 2006 was the only training they have received at the laboratory specifically focused on these topics. In terms of specific content, participants noted that they would like to see examples of what is considered *dual-use*, that there should be opportunities for discussion and questions, that content should change over time so that it remains relevant to training participants, and that different types of complementary training may be needed for different types of staff.

#### 3.4.2 Best and Most Useful Format for Such Training Materials

Focus group participants did not have one consensus recommendation for the best format for training materials. Instead they noted several related types of training formats that might be valuable to institute in the national laboratories, as shown in Table 2. The two most frequently recommended formats were web-based training included in existing annual training, training as a stand-alone module or as a webinar and/or in-person sessions, such as through brown bags. Participants saw these as potentially complementary methods. Web-based training has broad reach and can serve to raise awareness. The amount of training or content of training could also be tiered to group needs. However, participants were concerned that it might have low impact and that it might not be equally effective for those less familiar with dual-use issues (such as trainees or some managers).

In-person trainings are seen as valuable to staff who need a more in-depth awareness of dual-use issues. They also serve as a forum for discussion and interaction around *dual-use*. In-person trainings are seen as particularly valuable for training small groups that require specialized information, such as IBC members, ADCs, biosafety officers, and project managers. However, they could also be used for general training purposes. Potential barriers to this approach included the facts that it may not reach all staff that need it and that such trainings were logistically difficult to schedule.

Additional mechanisms to raise awareness were also mentioned by focus group participants. These included:

- *Brown Bags*. Incorporating *dual-use* as a topic in an existing brown bag series for staff such as those conducted by the project manager or NIH officer.
- *Institutional Biosafety Committees*. Provide educational material to help IBCs educate scientists about dual-use concerns in their research and any future changes to requirements or policies.
- *Inclusion in Requests for Proposals*. Inclusion of dual-use considerations in NIH-sponsored research was seen as a valuable way to bring these issues to greater prominence among researchers who are currently less aware.
- *Guidance websites*. Provide resources for staff to self-education. This could include directing staff to websites from existing groups such as NSABB.
- Culture change. Pursuing long-term cultural change where dual-use considerations are simply part of the way of doing business in the laboratory. The value of this concept was discussed in several groups. As one IBC member noted, "To me, culture change means getting out of that mentality [of only doing what is required] to one where just as a normal course of doing business as a scientist I will consider these issues."

In discussing training content: participants across groups recommended case studies as useful content to include in a training session. They could be included in either web-based approaches or in-person sessions. Participants suggested giving both extreme examples as well as more borderline examples. One approach suggested was to have readers score an article that has been flagged as potentially problematic by NSABB or other Federal agencies for dual-use concerns and have a discussion about the issues raised. Other suggestions related to training content and how it is conveyed included:

- Ensure that both the positive aspects of dual-use research are discussed as well as the potential negatives of such research;
- Ensure that researchers understand why dual-use concerns are relevant to their work and what the impact of inappropriate disclosure is or could be;
- Ensure that the content has personal relevance to the researcher and is not repeated every year;
- IBCs need knowledge of what to look for in regards to *dual-use* including guidance in discerning which issues are really of concern.

#### 3.4.3 Organizations Considered Appropriate to Develop and Deliver Such Training Materials

Focus group participants did not have strong opinions about which organizations could develop and deliver training material. They did, however, believe that it would be better to have centrally developed content that would be consistent across the national laboratories (or potentially even to university audiences) rather than having each institution independently develop content on this subject. Content developed and delivered by PNNL staff would be acceptable.

In addition, participants noted that content developed by NSABB or NIH would be valuable to IBCs as supplementary guidance on how they should review dual-use concerns. In addition, ensuring that training materials were developed consistently with emerging NIH guidance would help staff to understand that the laboratories were in compliance and what the emerging scientific consensus was related to *dual-use* and biosecurity considerations.

 Table 2. Training formats suggested by focus group participants

| Training Format   | Audience(s)   | Potential Benefits   | Potential Negatives  | Managers | IBC      | Scientists |
|---|---|--|--|----------|----------|------------|
| Incorporated into existing annual web-based training (e.g., safety training, ethics training, newcomer orientation, etc.) | All relevant staff – content might<br>be tiered by BSL level or other<br>criteria; off-site staff; also<br>appropriate for students/trainees  | Existing requirement so it will be done; easy to incorporate additional information; broad reach   | Staff don't retain information; quizzes for comprehension are generally easy to pass; not interactive; for ethics training this is offered to all staff not just those in the life sciences so it may not seem relevant to all.                                      | <b>√</b> | <b>√</b> | <b>√</b>   |
| Stand-alone web-based module  | Targeted to new staff or those who need more in-depth knowledge on the topic, such as IBC members   | Possibility for more in-depth presentation of information; not everyone needs to receive it; content can be tailored to different groups; less resource-intensive than sending people to off-site training | Staff don't retain information; quizzes for comprehension are generally easy to pass; if voluntary, people will not complete it; logistic difficulty in knowing which staff have completed it and conveying information to the training coordinator; not interactive | <b>*</b> | <b>✓</b> | <b>V</b>   |
| DVD presentation that takes participants through a dual-use scenario  |   | Gaining consensus on the content would be a helpful clarification on what constitutes dual-use   |  | <b>√</b> |          |            |
| Brown Bag/ in-person sessions   | Could be targeted to all relevant<br>staff; Could be held for IBC<br>members specifically; specific to<br>managers; ADC; biosafety<br>officer | Allows for discussion; encourages interaction around dual-use; may be incorporated into an existing series of discussions and offered by on-site staff   | Logistics difficult to coordinate; may not have a broad reach; could create difficulties if people with different clearance statuses are present   | <b>√</b> | <b>√</b> | <b>√</b>   |
| Webinars  | Could be targeted to all relevant staff   | Seen as a good way to present information as well as provide a discussion forum; conducted to geographically dispersed population  |  |          | <b>✓</b> |            |
| Hands-on training   | Students/interns  | Helps to retain information;<br>responsibility of PI or mentors to<br>conduct; if they learn it as students they<br>are prepared as new researchers  | Trainees may lack context for dual-use training because they are focused on methods  |          |          | <b>√</b>   |

#### 3.4.4 Likelihood That Materials Would Be Used If Developed

Focus group participants across groups thought that, if training were not mandatory in some way, then the likelihood individual researchers would self-educate would be used would be low. As one IBC member suggested, "With all of the constraints on the investigators' time, they're not going to take it unless there really is a personal interest or a requirement to do so." Suggestions for making it mandatory included including it in institutional requirements, such as a requirement of IBC review or in mandatory annual refresher trainings. Other suggestions included making it a requirement of funding from NIH rather than an institutional requirement similar to human subjects review certification requirements. The two types of requirements could also be tied, since if NIH makes it a requirement for scientists, then the institutions will have to find a way to comply.

#### 4. Conclusions and Recommendations

#### 4.1 Current Levels of Awareness

Based on the focus group responses, staff in the national laboratories have varying levels of awareness of dual-use and biosecurity considerations. A primary driver of awareness is the type of research conducted and whether it is considered to be of low risk or of high risk. While participants acknowledge the risks inherent in almost all types of life science research, in the absence of clear guidance and consensus in the scientific community about what actually constitutes dual-use research of concern, participants tend to be more concerned about security concerns in circumstances where the potential for dual-use is clear cut (e.g., Select Agent research) and where regulations and protections are already in place. In most other circumstances, they tend to see dual-use considerations as of minor concern; in these cases, greater importance is placed on furthering science and sharing research.

#### 4.2 Need for Increased Awareness

Focus group respondents identified a number of groups that could benefit from greater awareness of dual-use and biosecurity considerations and/or more training on more in-depth topics of related interest. Groups included scientists at the national laboratories, other individuals conducting research, including technicians and students; those involved in the review process, including IBCs, ADCs, biosafety officers, and managers; and the general public. The need for broader awareness of dual-use issues is highlighted by increased attention paid by Federal agencies as well as new guidance being developed by groups such as NSABB. With such changes on the way, scientists in the national laboratories and elsewhere who have not traditionally considered these issues may find increased awareness of dual-use and security issues both necessary and inevitable. They may also find that proactive early engagement facilitates cultural change and gives scientists a voice into the development of new guidelines.

In addition, focus group participants pointed out the challenges in identifying dual-use research of concern, and accurately assessing risk. They acknowledge that there is the potential for misuse of almost all life sciences research, but note that the uncertainties of scientific research make it difficult to characterize potential risks and benefits of conducting the science and publishing results. Thus, when the level of risk is unclear, participants tended to categorize it as a minimal, and pursue and publish research. Given this situation, focus group participants did see a need for additional guidance and clarity around what constitutes a dual-use concern. Increased awareness and training in this area seems both warranted and needed.

#### 4.3 Concerns Related to Guidelines and Codes of Conduct

Focus group participants believed that mandated guidelines and codes of conduct related to dual-use and biosecurity issues in the life sciences would be overly restrictive, burdensome, and unnecessary. Participants also noted that such guidelines would be difficult to enforce. Voluntary standards could help contribute needed clarity in this area and help raise awareness, but participants were also concerned that voluntary standard would drive regulations (which they view as negative). However, participants also recognized that if such regulations or guidelines were enacted, the laboratories would have to respond and react, and that new guidelines or future regulations would be a driver of awareness and a reason for scientists that have not been concerned about these issues to take notice. Additional guidance would be needed from NSABB/NIH/DOE regarding how a code of conduct and guidelines would be implemented and future implications they might have in the future.

#### 4.4 Training Materials

Most participants were open to the idea of future training in this area with the preference that, for most staff, it be included in existing training rather than constituted as a separate requirement. They also preferred that the information or level of training be tiered so that those who are conducting "lower risk" work not have the same requirements as those conducting work with higher dual-use potential. They also saw benefit in more interactive forums tailored to various groups of staff to address more specialized issues. A small minority of participants did not see any additional need for training on this topic.

Based on these results, we recommend a two-tiered approach to training that includes the development of content for inclusion in existing web-based annual training sessions for conduct on an individual level. We also recommend a more tailored webinar approach that can be customized for use with individuals across laboratories in various groups (e.g., IBCs, ADCs, managers, etc.).

However, regardless of the specific training approach selected, it is important to obtain management support, buy-in, and leadership. A clear message needs to be conveyed to staff at all levels as to why these are important issues, how it applies to their work, and how the institution views their level of responsibility related to this topic. Additionally, to implement a cultural change around dual-use considerations and biosecurity issues will require leadership and commitment on the part of parent institution.

# Appendix B1 Focus Group Moderator Guide

INTRODUCTION 10 mins

I would like to welcome you all and thank you for making time in your busy schedules to talk with us today. I am [Name] with Battelle [group/division]. My colleague [Name] from Battelle [group/division] is also on the line and will be taking notes today.

First, I'd like to give you a little background. In 2006, PNNL developed educational materials and conducted brown-bag seminars at nine of the national laboratories. These outreach and education seminars were designed to convey information and raise scientist awareness regarding the requirements of the Biological Weapons Convention, concerns regarding dual-use in the life sciences, and emerging discussions regarding codes of conduct.

We are now engaged in a follow-up process to:

- Determine what discussion has taken place in the labs related to the initial workshop, and gather additional feedback from laboratories.
- Discuss the best path forward for establishing a more wide-spread mechanism for education.
- Consider the appropriate best format for effective and widespread scientist education, and how best to integrate material into laboratory training systems.

To gather this data, we are conducting a survey and several focus groups with seminar participants and other laboratory POCs. Results will be used to qualitatively evaluate the function of the 2006 outreach and education seminars, and assess the value and need of future mechanisms to promote awareness and education of dual-use concerns in the life sciences.

I will be asking a series of questions about these topics. There are no right or wrong answers to these questions, just different points of view and different experiences. So don't be afraid to give your honest opinion or talk about an experience. It's important that we hear the range of ideas. Please feel free to agree or disagree with each other. That type of information is important to us. Also, you can choose not to respond to any question, and you may stop participating at any time. I will make sure that we stay focused on the topic. Also, I will keep the discussion moving so we can finish within the 2 hours we promised you.

We will be audio recording our conversation today, but no names or identifying information will be included in the reports we prepare and the audio files will be deleted when analysis is complete, so please feel free to share your opinions.

I'd like to begin by asking everyone to introduce themselves by first name only, and tell us which scientific discipline you're in.

GENERAL 30 mins

Thank you. Next, I'd like to ask you about biosecurity and possible risks to biosecurity.

Over the past several years, particularly following the terrorist attacks of September 11 and the subsequent anthrax attacks, there has been a growing concern that information and technology from life sciences research could be diverted for malicious purposes. The availability of materials, equipment, and technology to build, sustain, and advance offensive BW programs is growing with globalization of trade and research. The pervasiveness of biotechnology throughout the world increases the availability of agents and toxins, equipment, and expertise that could support a biological weapons program.

Because of increasing concerns, it is recognized that there needs to be increased awareness of biosecurity risks, dual-use experiments and technology, etc. The dual-use nature of life sciences makes it difficult to control BW-related materials in the same manner as nuclear materials (i.e. classification and export controls).

#### A few definitions:

**Biosecurity:** New biosecurity measures have been – and are being -- developed in order to mitigate security risks. While biosafety measures are designed to prevent accidental exposure to potentially harmful pathogens, biosecurity tries to prevent the theft or diversion of materials, technology, and information.

Dual-use: Dual-use research is legitimate research that has the potential to be diverted to producing a WMD, threatening public health and national security. Dual-use life sciences research can be applied in fundamental research, research in biodefense and biological countermeasures, and biological weapons.

#### **Dual-use CASE STUDIES (AS NEEDED)**

- Recent report warning that Synthetic biology' may be misused for 'bioterrorism'.

  "Scientists at the University of Nottingham have warned that 'synthetic biology' a technique popular for its ability to create artificial life by engineering organisms is at risk of damaging the ecosystem and being abused by terrorists. In a report, commissioned by the Biotechnology and Biological Sciences Research Council, the university researchers stress the need for new control and regulations on the use of synthetic biology, highlighting ethical and social concerns over the issue. They fear that synthetic biology may be misused to spread 'bioterrorism,' designing new organisms to be hostile to humans." Scientists have used new DNA synthesis technologies and open-source access to DNA sequence information to synthesize genomes of several viruses and bacteria, including the 1918 flu virus and poliovirus, without access to the organism.
- Mousepox IL-4 Experiments: Use the Australian experiments with the Mousepox virus as a case study. The research team was developing contraceptive vaccines for sterilizing mice and rabbits without killing them. The researchers modified the mousepox virus by adding a gene for a natural immunosuppressant called IL-4, expecting this would boost antibody production.
   Researchers inserted an IL4 gene into the virus expecting benign results; however, the mice died when treated with the vaccine strain. The modified IL-4 seemed to switch off a key part of the immune system (cell-mediated immune response), making the modified mousepox virus far more lethal than the unmodified version, and killing 60 per cent of vaccinated mice. This

study provides a clear example of how genetic recombination is capable of creating a virus (or other pathogens) with genes that allow the pathogen to overcome host defense and to spread with little or no control.

- Nanotechnology could also be used to deliver toxic agents maliciously. For example, one area
  has been in the advancement of aerosol delivery systems; these are now employed for
  vaccinations, drug therapy, recombinant proteins, and nucleotides.
- **Disposable lab equipment** (i.e. disposable bioreactors) can allow production of pathogenic material without a WMD "footprint."

#### **Questions:**

• US science has traditionally been seen as value-neutral – in your opinion, how aware are scientists of the dual-use nature of much of biological research? (Alternatively: Do you believe that the lack of awareness regarding the potential for dual-use of biological knowledge and materials creates a danger?)

#### For clarification, if needed:

- Who is sufficiently aware? Who is not?
- How would you describe the biosecurity risks involved in the kind of work you do? Do you think that your work could be misused by a person or group who wanted to do harm?

#### For clarification, if needed:

- What is your perspective of the biosecurity risks associated with life sciences research more broadly? How much of a biosecurity risk is there, in your opinion?
- What does it mean to be a responsible scientist when there is a possibility that the products or knowledge you generate could be misused?
- What considerations do you make in releasing your research methodology or results to the public?

#### For clarification, if needed:

- How else do you address the risk posed by dual-use technologies?
- Are there any long-term ramifications that you consider?
- Do you consider whether there is a "dual" use or another possibly dangerous use for your research results or methodology?
- Do you believe that trying to control the dissemination of information can help deter misuse of life sciences work for biological weapons?

30 mins

The National Science Advisory Board for Biosecurity (NSABB), an advisory body to the USG, was tasked with proposing an oversight framework for the "identification, review, conduct, and communication of life sciences research with dual-use potential." NSABB advises HHS and NIH, as well as the heads of all federal departments and agencies that support life sciences research. Part of this framework includes "considerations in developing a code of conduct for dual-use research in the life sciences", as well as recommendations for training in dual-use research.

In 2006, PNNL conducted a series of seminars for the national labs; you may have participated in these seminars. These seminars focused on the BWC, Dual-use concerns, and the possibility that the US government might promulgate guidelines for developing "Codes of Conduct" in the life sciences.

# Considering that NSABB developed guidelines will most likely be adopted by NIH and will therefore impact the national laboratories,

- What are your reactions to the general idea of a code of conduct? To dual-use guidelines? How might these affect the balance of promoting security and ensuring freedom of research?
- What types of needs do you see for increased awareness and education in some of the areas we've discussed, or mentioned by the NSABB group, that is, biosecurity, dual-use, codes of conduct?
- Has there been any increase in the overall awareness of biosecurity and dual-use concerns among your colleagues or within your organization over the past few years?

#### For clarification:

- What is the driver for increased awareness?
- Were the 2006 seminars helpful in raising awareness about the BWC, dual-use concerns, codes of conduct, and education and outreach?
- Alternatively: Would a seminar such as the one conducted in 2006 be helpful in raising awareness about the BWC, dual-use concerns, and codes of conduct?

Finally, I'd like to ask for your thoughts and recommendations related to tools for education and training, in light of the new guidelines being developed and promulgated.

- What critical gaps do you see in education and awareness that are not covered by existing guidance (including BMBL, IBCs, etc), for which additional training tools would be helpful in raising awareness of biosecurity concerns and dual-use risks?
- Assuming they were made available (and were free of charge), what types of tools would be most helpful for you in communicating this information to staff, other scientists, new hires, students and interns, etc.?
  - O What types of tools would you find helpful as you mentor and communicate with interns and new hires?
  - o What types of tools would be useful in maintaining awareness for scientists already in the laboratory system? For managers? For IBCs/IRBs, etc.?
  - o What groups might benefit most from these tools?

#### If needed:

What format would be most useful and effective for these tools?

- Web-based
- Reference manual/book
- Materials for classroom training
- Seminars
- Others?

(IF Web-based tools are selected:)

- How should the tools be delivered?
- In conjunction with existing biosafety modules? Independently?
- To be incorporated into annual training?
- To be delivered to PIs and junior staff on a per-project basis
- Are there other means or mechanisms that could most effectively raise awareness regarding the dangers of dual-use materials and knowledge, either conjunctively or alternatively? (e.g., readings and acknowledgment required by client, magazines and journals, computer training, DVD video, staff brownbag discussions, practical exercises, etc.)

#### Ways and means: (IF it's appropriate:)

- How frequently should training/refresher courses be delivered?
- How would you suggest we have junior investigators participate in workshops, seminars, or other educational venues?

• Culture of responsibility: T here has been some discussion about moving towards a "culture of responsibility". Are there additional means that you would propose to promote such a culture of responsibility related to safety, security, and bioresponsibility?

#### **CLOSING**

Thank you so much for your thoughts and recommendations. Your input is very important to this process. Before we close, is there anything else you would like to share about this topic that we have not already covered?

Thanks again for participating today. Please let us know if you are interested in the analysis of these results.

# Appendix C Crosswalk Analysis Report

## **Education and Outreach in the Life Sciences**

## **Crosswalk Analysis Report: Survey and Focus Group Findings**

October 2008

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#### 1. Introduction

Rapid developments in biotechnology and the life sciences bring significant benefits, but also create new security challenges. In recent years, members of the scientific and security policy communities have raised concerns about the potential for misuse of knowledge, tools, and techniques for purposes of bioterrorism. Such research is sometimes called "dual-use" research because, although the research is intended for beneficial purposes only, it could be misapplied. The role of scientists, institutions, scientific societies, and the government is critical in fostering an environment that enhances both the scientific enterprise and national security.

In 2004, the U.S. government established the National Science Advisory Board on Biosecurity (NSABB) under the auspices of the National Institutes of Health (NIH) to contemplate the possibility and impact of greater oversight for life sciences research to prevent or mitigate deliberate misuse. Similarly, the U.S. Department of Energy (DOE) is considering how to respond to emerging issues of concern related to dual-use. Other federal agencies are planning to issue further guidelines and considering additional policies regarding responsible scientific research. Discussion sessions on this topic were also conducted by Pacific Northwest National Laboratory (PNNL) for the DOE's Office of International Regimes and Agreements (NA-243) at ten of the national laboratories in Fall of 2006.

The DOE's National Nuclear Security Agency (NNSA) asked PNNL to consider the role of individual scientists in upholding safety and security. The views of scientists were identified as a critical component of this policy process. Therefore, scientists, managers, and representatives of Institutional Biosafety Committees (IBCs) at the national labs were invited to participate in a brief web-based survey that was designed to:

- Evaluate the function of the 2006 outreach and education seminars that were conducted by the U.S. DOE;
- Assess the opinions of scientists about potential future mechanisms to address dual-use concerns in the life sciences community;
- Gather data on scientists' attitudes toward potential security risks from agricultural, public health, and biomedical research;
- Give scientists a voice in the policy-making process.

In addition, three focus groups were conducted with scientists, managers, and IBC representatives to discuss some of the questions related to education, outreach, and codes of conduct in further detail and gather additional input on biosecurity and dual-use awareness at the laboratories. The overall purpose of this process was to identify concerns related to these topics and to gather suggestions for creating an environment where both the scientific enterprise and national security are enhanced.

The information gathered through the survey and focus groups will be instrumental in informing the U.S. position at the Biological Weapons Convention (BWC) Experts' Group meeting in August 2008, as well as in moving toward a sustainable mechanism for biosecurity education and awareness. The information will also guide DOE action in developing educational tools that will help promote a laboratory culture of responsibility.

#### 2. Methods

To recruit individuals for the web survey and the focus groups, the PNNL Project Director sent email invitations to individuals who participated in the 2006 Outreach and Education Training and other points of contact at each of the national laboratories (N=202). Of these invitations, 173 were delivered and 29 were returned as undeliverable. The web survey email invitation introduced the purpose of the survey and invited individuals to participate by clicking on a hyperlink. Individuals were also encouraged to forward the survey link to others who might be interested in participating. Several follow-up emails were sent to the entire sample encouraging participation. After removing two cases with incomplete responses for most of the survey questions, the final sample from the web survey consisted of 47 respondents.

The focus group email invitation described the purpose of the focus groups and invited individuals to participate in a focus group for managers, scientists, or IBC representatives. Each of these groups was offered a choice of times, and the date and time that was convenient for the majority of individual participants was selected for each of the three groups. Additional follow-up emails were sent to points of contact at each of the laboratories to encourage participation. The following table summarizes the final focus group participation.

| Focus Group Type    | Date          | # of<br>Participants | Labs Represented                           |
|---------------------|---------------|----------------------|--|
| Scientists          | June 11, 2008 | 5                    | Brookhaven, Los Alamos, Oak<br>Ridge, PNNL |
| Managers            | June 12, 2008 | 5                    | Idaho, Los Alamos, NREL,<br>PNNL           |
| IBC representatives | June 18, 2008 | 5                    | Berkeley, Los Alamos, Oak<br>Ridge, Sandia |

In addition, comments provided by three individuals who were not available to attend the IBC focus group were integrated into the analysis.

#### 3. Results

This report provides cross-cutting findings from the survey and focus groups results. In particular we highlight areas of convergence across these two methodologies and describe how the results from these two methods complement each other.

#### 3.1 Awareness of Dual-Use Risk

#### 3.1.1 Current Level of Awareness

Survey results found that about half of the participants considered that they were *currently* conducting or managing research with dual-use potential (50%), while slightly over half reported that they had worked with or managed research using Select Agents (57%) at some point. Very few participants were currently conducting or managing research that included the types of experiments anticipated as needed special review under NSABB guidelines (4%).

Survey results showed that most participants were familiar with the Biological Weapons Convention (89%); fewer participants were familiar with the provisions of the BWC for biosafety and biosecurity

(63%) or with BWC Article IV as it introduces the concept of individual responsibility for upholding and promoting nonproliferation obligations (64%). The survey also found that those respondents who had conducted Select Agent research were generally more aware of the BWC (100% versus 75%), its provisions for biosecurity and biosafety (65% versus 45%), and Article IV (69% versus 60%) than were those who had not conducted such research.

These survey findings reflected the consensus among focus group participants on this topic. Consistently, focus group participants thought there would be greatest awareness of dual-use issues among those conducting research with a perceived "high" risk for dual-use potential versus those conducting research with lower risk. Individuals who were generally considered to be more aware of dual-use considerations included those conducting work with Select Agents or with organisms at higher than Biosafety Level 2 (BSL2) rating, or those working for national security clients.

#### 3.1.2 Responsibilities of Scientists

Survey respondents were asked to assess the possibility that several types of actions by scientists or institutions would minimize the potential threat to national security posed by dual-use research. Survey findings indicate general support for the idea that if scientists conduct a review of their own work for dual-use considerations (79% agree or strongly agree) or provide formal assurance to their institution that they were conducting such an assessment (60% agree or strongly agree) it would serve to minimize potential threat. In addition, there was slightly higher agreement (47%) than disagreement (43%) with the view that research review by an appropriate individual or board (such as an IBC) would help to mitigate risk and that classifying research findings on dual-use could minimize the potential threat (46% agree/strongly agree versus 31% disagree/strongly disagree).

Focus group participants were asked more generally about actions consistent with being a "responsible scientist" given the potential for dual-use in the life sciences. Across groups there was support for the idea that Principal Investigators (PIs) had responsibility to review the potential for dual-use in their own work. However, focus group participants also stressed that in the national laboratory context, minimizing risk related to potential dual-use is actually a responsibility shared among the PI, the IBC, Institutional Review Boards (IRBs), the biosafety officer, the authorized derivative classifier (ADC), project managers and line managers that approve of proposals, and other institutional controls.

Survey respondents were split over whether placing some restrictions on the dissemination of research findings would help to minimize the potential threat posed by dual-use research. Similar percentages agreed versus disagreed with statements about placing restrictions on disclosure of research details through personal communication (37% versus 39%), altering or removing experimental methods or findings prior to publication or presentation (43% versus 39%), or restricting the publication of findings based on dual-use potential (36% versus 41%).

These results were contradicted to some extent by the focus group respondents, who felt that those conducting research with Select Agents or pathogens already took certain precautions against inappropriate publication of findings, and felt that additional restrictions were not necessary – or would be impossible to enforce and tend to hamper scientific research. In addition, for those conducting "low" risk research, scientists believed that, as long as common sense measures were followed, additional mandatory restrictions were unnecessary and potentially detrimental to advances in science.

#### 3.2 Factors that Influence Changes in Awareness or Changes in Behavior

A majority of survey respondents had participated in discussions about dual-use research and codes of conduct (68%). Among these respondents, new or emerging guidelines addressing dual-use research, personal reading or research, and the 2006 Outreach and Education Training provided by PNNL staff were cited as drivers for these discussions. A percentage (23%, N=11) of respondents also indicated that they had changed their behavior related to bioterrorism concerns in the last two years. Of these 11 respondents, most of the types of changes made related to *how information is disseminated* through personal communication, conference presentations, or modification of a manuscript; rather than through the *avoidance* of collaboration, conducting particular research, or providing information at all. Though cited by small numbers of respondents, the same set of factors – new or emerging guidelines, personal reading, and the 2006 training – were most often cited as contributing to behavioral changes. This underscores that, despite the basic safety and security measures in place at national laboratories, there is value to providing education related to dual-use.

Focus group participants were fairly evenly split between those who had observed an increase in awareness of dual-use in their laboratory in the past few years versus those who had not seen a change. Factors most often cited by participants who had observed increased awareness included the 2006 Outreach and Education Training, issues in the popular media or publications of concern, discussion around proposals, or client directives or regulations regarding dual-use work.

#### 3.3 Codes of Conduct and Guidelines

Survey participants were asked about their level of awareness of journal policies regarding potential dual-use and their opinions about having guidelines for journals or codes of conduct for professional societies. Almost one-half of respondents (43%) did not know about the proportion of journals requiring review regarding dual-use. However, there was widespread agreement that journals should have such guidelines (83% agree or strongly agree). Similarly, respondents were largely unaware about whether the professional societies to which they belonged had codes of conduct for members around dual-use (44%), but did agree with this idea (83% agree or strongly agree). Finally, survey respondents disagreed that providing greater Federal oversight of dual-use research would help to mitigate potential threat (61% disagree or strongly disagree).

Focus group participants largely echoed these views. Those who had been journal reviewers reported that existing dual-use guidelines are sometimes inadequate, and some mentioned anecdotes of articles they have seen over the years that they thought had dual-use potential but that were nevertheless published in the peer-reviewed literature. Focus group participants were not specifically asked about professional society codes of conduct, although they did express the view that a mandatory code of conduct (such as from the Federal government) would be viewed as negative. However, some focus group participants did see value in voluntary guidelines or codes of conduct to clarify the scientific community consensus on what constitutes dual-use and what scientists should be aware of in this arena.

#### 3.4 Training

More than one-half of the survey respondents (57%) participated in the 2006 Outreach and Education Training. The focus groups also included some individuals who had participated in the training. Both

survey and focus groups respondents were asked about which groups may benefit from additional training in dual-use concerns and what training formats would be preferred.

#### 3.4.1 Perceived Need for Training

Providing additional training on scientist obligations under the BWC, dual-use risks, and codes of conduct was seen as appropriate for a wide range of groups. Well over one-half of respondents saw the value of training for senior research scientists (83%), program/project managers (79%), IBC/IRB chairs and members (76%), mid-level research scientists and laboratory managers (76% each), and junior scientists (60%). There was less support for training of research associates/technicians (36%). Approximately half of the respondents agreed that mandatory training by institutions for scientists would help to mitigate dual-use risk (51% agree or strongly agree). A few respondents (6%) did not see any need for additional training.

Focus group participants also noted the groups listed by survey participants as appropriate targets for additional training. In addition, they saw some value in training of trainees and interns, security officers, authorized derivative classifiers, and foreign nationals. A few scientist participants expressed the view that no additional training was needed.

Both survey respondents and focus group participants expressed the view that university students and researchers could benefit from additional training on and awareness of dual-use concerns. Survey respondents thought that such a move would help to reduce the risk that research may pose to national security (74% agree or strongly agree). Focus group respondents cited universities as an area to target for training because of the perception that, since they operate under fewer restrictions than do the national laboratories, researchers in these settings were less aware of these issues. Training students early in these issues would be helpful as they begin their science careers.

#### 3.4.2 Training Format

Survey respondents overwhelmingly preferred web-based training (81%) to classroom training or a reference book (9% each). Focus group participants did not reach a consensus on the type of training format that would be most valuable. The two most frequently recommended formats were web-based training and in-person sessions, such as brown bags. In general, they saw web-based training as applicable to training for all or most staff, especially if content could be tiered based on the type of research conducted, while in-person sessions were seen as potentially more valuable for particular groups of staff, such as IBC members or managers who might have more specific concerns.

#### 4. Conclusions and Limitations

The two methodologies – web survey and focus groups – were used to effectively obtain information about individuals' awareness of dual-use risks; perceptions of the need for training; and opinions about roles, responsibilities, and preventive measures related to life sciences research. In general, the survey and focus groups yielded similar results, with the focus group findings helping to inform the interpretation of the survey results. For example, both sets of results show variation in awareness of dual-use issues. Although the survey focused primarily on assessing the awareness of respondents themselves, the focus group protocol also asked respondents about their perceptions of the awareness levels of various key groups. Focus group respondents expressed the idea that levels of awareness may vary not only

according to whether one is working with Select Agents, but also according to other parameters, such as whether one is working with national security clients versus on NIH-funded research. This type of subtle variation was best obtained via the open discussion format of a focus group. As another example, survey respondents were asked to select their most preferred training format and overwhelmingly selected a webbased approach, whereas focus group participants further indicated support for other types of training in different situations, particularly training sessions involving live discussion for topics that needed more indepth coverage.

The overlap of findings existed in other areas as well, with survey and focus group questions obtaining similar information in different ways. In the survey as in the focus group, respondents were asked to identify groups they thought should participate in training covering life sciences research risks. Similar groups of potential trainees were noted under both methodologies (e.g., scientists, managers, IBCs, university students). One benefit of having a list of groups for respondents to choose from in a survey is that it yields a distribution which can indicate whether some groups were considered to be in greater need of training than others. Factors influencing changes in behavior and awareness, as well as opinions about codes of conduct and guidelines, were comparable across the survey and focus group findings.

A common theme in the results of the survey and the focus groups was that additional mandatory restrictions on scientists and the dissemination of research were viewed as negative. This information was elicited differently in the two modes. In the web survey, respondents were asked to evaluate the effectiveness of certain actions in minimizing *the potential threat to national security*. Actions included: having Principal Investigators conduct initial evaluations of the dual-use potential of research, requiring certification for researchers conducting some dual-use research, and providing greater federal oversight of dual-use research.

In the focus groups, participants were asked about actions associated with being a *responsible scientist* when there is a possibility that the products or knowledge one generates could be misused. It is clear that individual respondents believe that scientists should act responsibly by evaluating their research for dualuse potential and taking precautions when discussing research or disseminating results. However, focus group findings suggest that most national laboratory researchers consider that they are already acting responsibly in this regard and that additional restrictions would restrict scientific progress. Neither surveys nor focus groups indicated that it additional regulations or oversight is necessary.

The study has several limitations that should be noted. First, both the survey and the focus groups addressed areas related to education, training, and information sharing. Participants were not asked to discuss other types of actions that could reduce the threat, or the value of education, etc. in relation to these other mechanisms.

Also, it is possible that the samples obtained for the web survey and focus groups do not reflect the general opinions of scientists, managers, and IBC representatives across the national laboratories. Focus group findings by their nature allow an in-depth look at the opinions of various groups but cannot be generalized to the entire population. In addition, the response rates for the survey are relatively low. Only about 27% of those who were delivered emails completed the web survey. Email was the primary mode of follow-up used to encourage participation, although some managers and points of contact at some laboratories did encourage staff in their groups to participate. Overall, it is likely that participants were self-selecting due to specific interest in the subject matter, which may skew results. This may mean that awareness is even lower than indicated by the survey and focus groups, that there is a relatively low

level of concern regarding biosecurity, or that scientists do not want to engage in conversations about biosecurity (lack of time, concern about development of rules and regulations, etc.).

Finally, the survey and focus group participants were drawn from the same pool of individuals, thus convergence between survey and focus group results should not be interpreted as the convergence of opinions across distinct groups.

Overall, however, the focus group and survey responses were largely comparable and provide valuable insight into the opinions and preferences of national laboratory scientists regarding training on dual-use research, the BWC, and codes of conduct.





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